#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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### FORM 10-K



ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES LAVID For the fiscal year ended December 31, 2007

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number 000-52045



(Exact Name of Registrant as Specified in its Charter)

33-0928885

(I.R.S. Employer Identification Number)

95670

(Zip Code)

Registrant's telephone number, including area code: 1-800-228-4728

Securities registered pursuant to Section 12(b) of the Act:

Name of each exchange on which regi

Title of each class

Delaware

(State or Other Jurisdiction of

Incorporation or Organization)

2870 Kilgore Road

Rancho Cordova, California

(Address of Principal Executive Offices)

Common Stock, \$0.001 per share par value The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 🗆 No 🛛

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. 

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 🗸 No □

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained. to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer □ Accelerated filer ☑ Non-accelerated filer □ Smaller reporting company □ (Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No ☑

The aggregate market value of the voting common equity held by non-affiliates of the registrant, based upon the closing price of a share of the registrant's common stock on June 29, 2007 (which is the last business day of registrant's most recently completed second fiscal quarter), as reported on the NASDAQ Global Market was approximately \$488.3 million. Shares of common stock held by each executive officer and director and by each person who owns 5% or more of the outstanding common stock as of June 29, 2007 have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

At March 7, 2008, 47,098,328 shares of Common Stock, par value \$0.001, of the registrant were outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III of this Form 10-K incorporate information by reference from the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission by no later than April 29, 2008.

## ${\bf VOLCANO\ CORPORATION} \\ {\bf ANNUAL\ REPORT\ ON\ FORM\ 10-K\ FOR\ THE\ YEAR\ ENDED\ DECEMBER\ 31,\ 2007}$

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This annual report on Form 10-K contains forward-looking statements regarding future events and our future results that are based on current expectations, estimates, forecasts, and projections about the industries in which we operate and the beliefs and assumptions of our management. In some cases, you can identify these "forward-looking statements" by words like "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of those words and other comparable words. These statements include, but are not limited to, those concerning the following; our intentions, beliefs and expectations regarding our future financial performance, anticipated growth and trends in our business; the timing and success of our clinical trials and regulatory submissions; our belief that our cash and cash equivalents will be sufficient to satisfy our anticipated cash requirements; our operating results; our expectations regarding our revenues and customers; our distributors and statements regarding market penetration and expansion efforts. Forward-looking statements are subject to risks and uncertainties that could cause actual results and events to differ materially. For a detailed discussion of these risks and uncertainties, see the "Risk Factors" section of this Form 10-K. Any forward-looking statement speaks only as of the date on which it is made, and except as required by law, we undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-K.

We currently have registered trademarks for, at least, Volcano®, Eagle Eye®, Visions®, Revolution®, ComboWire®, SmartMap®, ComboMap®, SmartWire®, FloWire®, WaveWire®, VH®, Trak Back®, FloMap®, ChromaFlo® and Avanar®, and are in the process of registering certain other of our trademarks with the U.S. Patent and Trademark Office including, but not limited to, vfusion powered by Volcano<sup>TM</sup>, vfusion<sup>TM</sup>, AIM<sup>TM</sup>, Safe and Sound<sup>TM</sup> and SpinVision<sup>TM</sup>. Other brand names or trademarks appearing in this Annual Report are the property of their respective holders.

#### PART I

#### Item 1. Business

#### Overview

We design, develop, manufacture and commercialize a broad suite of intravascular ultrasound, or IVUS, and functional measurement, or FM, products that we believe enhance the diagnosis and treatment of vascular and structural heart disease. Our IVUS products consist of consoles, single-procedure disposable catheters and advanced functionality options. FM devices measure the pressure and flow characteristics of blood around plaque thereby allowing physicians to gauge the plaque's impact on blood flow and pressure. Our FM products consist of pressure and flow consoles and single-procedure disposable pressure and flow guide wires.

We market our products to physicians and technicians who perform percutaneous interventional procedures in hospitals and to other personnel who make purchasing decisions on behalf of hospitals. Our IVUS consoles are marketed as stand-alone units or customized units that can be integrated into a variety of hospital-based interventional surgical suites called cath labs. We have developed customized cath lab versions of these consoles and are developing advanced functionality options as part of our vfusion cath lab integration initiative. With the commercialization of our s5i and s5i GE Innova IVUS consoles and upon the commercialization of other new products and technologies, our vfusion offering will include cath lab-integrated IVUS and FM capabilities, our real-time Virtual Histology, or VH, IVUS functionality with color-coded identification of plaque composition, and automatic drawing of lumen and vessel borders. Our vfusion offering will also support IVUS integrated with other interventional devices, such as Medtronic's Pioneer re-entry device, used to cross lesions that are completely blocked, and our own image guided therapy products that are in development. The significantly expanded functionality of our vfusion offering will allow for networking of patient information, control of IVUS and FM information at both the operating table and in the cath lab control room, as well as the capability for images to be displayed on standard cath lab monitors. We expect to continue to develop new products and/or acquire technologies to expand our vfusion offering.

We have direct sales capabilities in all major geographies. As of December 31, 2007, we had 98 direct sales and support professionals in the United States, 15 direct sales and support professionals in Europe, 11 direct sales and support professionals in Japan and two direct sales and support professionals responsible for Asia, the Pacific Ocean

region and Latin America countries. In addition, we have approximately 50 distribution relationships in 40 other countries.

During the year ended December 31, 2007, we generated worldwide revenues of \$130.6 million and incurred an operating loss of \$33.1 million, which included a \$26.2 million expense of in-process research and development purchased as part of the CardioSpectra, Inc. (CardioSpectra) acquisition. As of December 31, 2007, we had a worldwide installed base of over 2,400 IVUS consoles and over 800 FM consoles. We intend to grow and leverage this installed base of consoles to drive recurring sales of our single-procedure disposable catheters and guide wires, which accounted for approximately 75% of our revenues during the year ended December 31, 2007.

#### **Our Strategy**

We offer a broad suite of IVUS and FM products that we believe enhance the percutaneous interventional diagnosis and treatment of vascular and structural heart disease by improving the efficiency and efficacy of existing percutaneous interventional procedures and by enabling important new therapeutic solutions. We believe that the clinical information provided by our products improves the diagnosis and treatment of vascular disease by aiding interventionalists in identifying diseased arteries, selecting a course of treatment, positioning a therapeutic device, treating diseased sites and assessing treatment results. Our technologies represent important advancements in the ongoing trend towards percutaneous interventional therapeutic procedures in the cath lab and provide substantial, clinically important improvements and cost efficiencies over existing methods. Our products seek to deliver all of the benefits associated with conventional IVUS and FM devices, while providing enhanced functionality and proprietary features that address the limitations associated with conventional forms of these technologies.

- Accelerating the trend towards less invasive procedures. Our IVUS products offer continuous, real-time
  three-dimensional imaging, plaque visualization, color-coded identification of plaque composition, and
  automatic drawing of lumen and vessel borders allowing for automatic vessel sizing. Our FM products offer
  physicians a simple pressure and flow based method to determine whether stenting or additional percutaneous intervention is required. We believe our combination of IVUS enhancements and functional
  assessment is instrumental in facilitating less invasive procedures.
- Improving the diagnosis of cardiovascular disease. We believe our VH IVUS products will significantly
  improve the diagnosis of cardiovascular disease by addressing the limitations of diagnostic angiography.
  Our ongoing VH Registry is exploring the correlation of plaque characteristics with patient demographics,
  clinical presentation and cardiac risk factors, which in conjunction with the PROSPECT data we believe
  will allow clinicians to identify patients and lesions at risk for future adverse coronary vascular system
  events.
- Improving the outcomes of percutaneous interventional procedures. We believe our products, enabled with novel technological enhancements, provide clinically significant information that improves the outcomes of current and increasingly complex percutaneous interventional procedures.
- Enabling new procedures to treat CAD, PAD and structural heart disease. Current treatment of a
  number of vascular and structural heart diseases, including coronary, peripheral and carotid artery disease
  and atrial fibrillation, a heart rhythm disorder involving a rapid heart rate in which the upper chambers, or
  atria, are stimulated to contract in a disorganized and abnormal manner, is limited by conventional catheterbased techniques and angiography. Because our technologies address many of these current limitations, we
  believe our products provide the potential to enable these diseases to be diagnosed and optimally treated
  percutaneously.
- Improving ease of use of IVUS technologies to drive market adoption. We believe our products, especially our recent IVUS product enhancements such as automatic real-time drawing of lumen and vessel borders, automatic vessel sizing, and color-coded identification of plaque composition, allow doctors to use IVUS with less training while still providing substantially more and better information. Our products also help physicians to conduct increasingly complex percutaneous procedures.
- Decreasing the number of interventional devices used per procedure and optimizing their usage. FM
  products offer the opportunity to physiologically assess lesion severity and determine whether stents are

needed. Additionally, our image guided therapy products have imaging capability. As a result, our IVUS and FM products have the potential to reduce the number of devices deployed thereby lowering treatment costs. IVUS provides the interventionalist the information to optimize stent sizing and placement.

Our goal is to establish our IVUS and FM products as the standard of care for percutaneous interventional diagnostic and therapeutic procedures. The key elements of our strategy for achieving this goal are to:

- Increase market share in existing IVUS and FM markets. We continue to introduce product enhancements to meet physicians' needs for improved visualization, characterization, and ease of use. We believe these enhancements make our products easier to use than competing products while providing substantially more and better information to improve procedural outcomes, thereby driving greater usage of our IVUS and FM products within the existing percutaneous interventional market.
- Increase IVUS and FM adoption rates. We are working on three strategies to increase penetration. First, we have addressed limitations of conventional IVUS such as difficulty in use, lack of automation and grayscale imaging by developing technologies and introducing features such as automatic real-time drawing of lumen and vessel borders, color-coded identification of plaque composition, and automatic vessel sizing. Second, we developed PC-based IVUS and FM consoles that can be integrated easily into cath labs, thereby making it easier for physicians to adopt and use our products. Third, we have pursued collaborations such as our agreement with General Electric Medical Systems Scs, or GE, in which our integrated IVUS products are required to be included on all of GE's initial quotes for cardiovascular and interventional radiology systems.
- Leverage our installed base to drive single-procedure disposable device revenues. We intend to grow
  and leverage our installed base of IVUS and FM consoles to drive recurring sales of our single-procedure
  disposable catheters and guide wires to increase our recurring revenue stream from sales of our singleprocedure disposable products to our installed base.
- Develop clinical applications for and utilization of our technology in new markets. We plan to leverage our current technology to expand into new markets and increase clinical applications through clinical studies, conducted by us or with other companies. We have several programs underway to expand the use of our technology in percutaneous interventional procedures and drug studies. These include (1) establishing the use of our IVUS products in combination with diagnostic angiography, (2) developing the capability to determine optimal treatment options for those patients who have stents placed and are on anti-platelet drug therapy, (3) developing technology supported by clinical data to diagnose and guide treatment of vulnerable plaque and carotid artery disease, (4) developing a family of intracardiac echo products based on our existing technologies to improve treatments of structural heart disease, (5) integrating the imaging capability of IVUS with coronary and peripheral therapeutic devices, and (6) using our current technologies in on-going or planned drug studies conducted by pharmaceutical and biotechnology companies.
- Enhance product capabilities and introduce new products through collaborations or acquisitions. We have a successful track record of acquiring and licensing technologies and collaborating with third parties to create synergistic product offerings. For instance, we licensed from The Cleveland Clinic Foundation the VH IVUS technology that now forms the core of our ability to determine the composition of plaque and acquired from Philips the intellectual property rights allowing us to develop our Revolution rotational catheter. In December 2007, we acquired CardioSpectra, Inc. whose core product line, based on innovative Optical Coherence Tomography (OCT) technology, is expected to complement our existing product offerings. In addition. We believe there will be additional opportunities to leverage these capabilities through technology or company acquisitions as well as collaborations.
- Improve manufacturing efficiencies and reduce costs to improve margins. We believe that by moving
  to PC-based consoles and improving our manufacturing processes through increased automation and
  design improvements, we will be able to continue to reduce the cost to manufacture our consoles and
  single-procedure disposable products.
- Continue to expand and protect our intellectual property position. As of December 31, 2007, we had a
  broad portfolio of at least 191 owned or licensed U.S. and international patents and 154 applications for

owned or licensed patents. We intend to continue to expand our intellectual property position to protect the design and use of our products, principally in the areas of IVUS and FM for the diagnosis and guidance of treatment of vascular and structural heart disease.

#### **Our Products**

Our products include IVUS and FM consoles, IVUS catheters, FM guide wires and advanced functionality options. Our consoles are marketed as stand-alone units or units that can be integrated into the cath lab. We market the integrated cath lab version of these consoles and advanced functionality options as part of our vfusion cath lab integration initiative. Our s5i console is made up of components that can be customized to each cath lab's specifications and integrated into virtually any cath lab. Our s5i GE Innova IVUS console is specifically designed and manufactured for GE to integrate into GE's Innova cath labs. With the commercialization of our s5i and s5i GE Innova IVUS consoles and upon the commercialization of other new products and technologies, our vfusion offering will include cath lab-integrated IVUS and FM capabilities, real-time VH IVUS functionality with color-coded identification of plaque composition and automatic real-time drawing of lumen and vessel borders. Our vfusion offering will also support IVUS integrated with other interventional devices, such as Medtronic's Pioneer re-entry device, used to cross lesions that are completely blocked. The significantly expanded functionality of our vfusion offering will allow for networking of patient information, control of IVUS and FM information at both the operating table and in the cath lab control room, as well as the capability for images to be displayed on standard cath lab monitors. We expect to continue to develop new products and technologies to expand our vfusion offering.

#### **Our IVUS Products**

#### Consoles

We design, develop, manufacture and commercialize consoles that are proprietary, high-speed electronic systems that process the signals received from our IVUS catheters. These consoles generate high-resolution images which can be displayed on a monitor and can be permanently stored on the system or another medium. We have a family of consoles including our IVUS In-Vision Gold, or IVG, and the new PC-based s5. The s5 family of consoles, which became our primary console following its full commercial launch in July 2006, is substantially smaller, lighter and less expensive to manufacture, and has enhanced functionality. The s5 family has four different models:

- s5: This portable and mobile console is the lightest product on the market, and we believe it has the simplest and easiest user interface. The s5 weighs 95 pounds compared to greater than 300 pounds for our IVUS IVG console and Boston Scientific's Galaxy product.
- s5i: This console is made up of components that can be customized to each cath lab's specifications and integrated into virtually any cath lab while retaining the full functionality of the s5. When the s5i is integrated into the cath lab, it works seamlessly with the workflow of the cath lab in terms of manipulating and archiving patient images and data.
- s5i GE Innova IVUS: This console is designed and manufactured to be integrated into GE's Innova cath labs. It is made up of the same components and functionality of an s5i for customization with each cath lab's specifications. Additionally, GE's Innova system has a touch screen controller that is located on the cath lab patient table to control the functions of the cath lab, including our IVUS functionality.
- s5 and s5i with FFR: These consoles are identical to the s5 and s5i, except that they also include the functionality to measure pressure and FFR.

#### Catheters

Our single-procedure disposable catheters only operate and interface with our family of IVUS consoles. We are the only company that offers both phased array and rotational catheters following the commercial launch in the third quarter of 2006 of our Revolution rotational IVUS catheter. We believe this allows us to meet the needs of a greater number of physicians than our competitors. Each phased array IVUS catheter contains a cylindrical transducer array with 64 elements capable of separately sending and receiving signals. Our 45 MHz Revolution rotational catheter is the highest frequency catheter on the market and we believe it offers better resolution in the area close to the end of

the catheter, or near-field, than competitive rotational catheters. The Revolution develops images by rotating a single transducer element inside the tip of the catheter using a flexible torque cable. Our Eagle Eye Gold, Visions PV .018, Visions PV 8.2 and Revolution catheters vary in their principal use, frequencies, shaft sizes, shaft lengths, guide wire compatibility and distal tip lengths. These differences allow for the use of different catheters in various portions of the vascular system.

#### Advanced Functionality

Our IVUS products incorporate key features that add valuable clinical functionality addressing a number of the historical limitations of conventional IVUS and we intend to incorporate additional functionality in the future. Our IVUS products now incorporate ChromaFlo and VH IVUS which contains *in vivo* color-coded identification of plaque composition and automatic drawing of lumen and vessel borders.

#### ChromaFlo

Angiography alone does not always identify malapposed stents because the contrast injection that makes the lumen visible on x-ray can flow inside the stent, and in between the stent and vessel wall. When this occurs, the stent struts are too small to compete with the dark lumen of the x-ray, leaving the two dimensional image inconclusive or misleading. ChromaFlo stent apposition analysis uses sequential IVUS frames to differentiate circulating blood from stationary or anchored tissue, and when enabled, highlights moving blood in orange. ChromaFlo is particularly important when assessing stent placement as the detailed cross-sectional image clearly identifies moving blood inside and outside of the stent lumen, prompting physicians in many cases to expand the stent until all of the orange colored blood appears inside of the stent lumen.

#### VH IVUS

Conventional IVUS allows the visualization of atherosclerotic plaque. However, in standard IVUS grayscale images, calcified regions of plaque and dense fibrous components generally reflect ultrasound energy well and thus appear bright and homogeneous. Conversely, regions of low echo reflectance are usually labeled as soft or mixed plaque. However, the visual interpretation is limited and does not allow qualitative and quantitative real-time assessment of plaque composition. This makes reading IVUS images difficult, drawing lumen and vessel borders cumbersome and identifying vulnerable plaque not possible. Our VH IVUS product allows for the first time, easy to read and interpret IVUS images with color-coded identification of plaque types. Additionally, a key element of the VH IVUS product is the capability to provide automatic drawing of lumen and vessel borders. This feature enables automated vessel sizing, which makes it easier and faster to use our IVUS products. Finally, our VH IVUS functionality offers the potential to identify vulnerable plaque alone or in conjunction with other techniques.

The following table summarizes our recent and anticipated upcoming IVUS related product launches:

Product	Expected European Launch Date	Expected U.S. Launch Date	Expected Japanese Launch Date
Consoles			
s5 grayscale	Launched	Launched	Launched
s5 with VH IVUS	Launched	Launched	Launched
s5i with VH IVUS	Launched	Launched	Launched
s5i GE Innova IVUS with VH IVUS	Launched	Launched	
s5 and s5i with FFR	1H 2008	1H 2008	2H 2008
Catheters			
Revolution on IVG consoles	Launched	Launched	Launched
Revolution on s5 family of consoles	1H 2008	· 1H 2008	2H 2008
Revolution supporting VH IVUS on s5	1H 2009	1H 2009	2H 2009
IVUS Guided Balloon	1H 2009	2H 2009	2H 2010

#### **Our FM Products**

Our FM products consist of pressure and flow consoles and single-procedure disposable pressure and flow guide wires. We believe we are the only company that offers a full line of pressure and flow guide wires as well as a guide wire that can measure both pressure and flow. Our consoles are mobile, proprietary and high speed electronic systems with different functionalities and sizes designed and manufactured to process the signals received from only our guide wires.

#### **Product Expansion**

#### Our Vulnerable Plaque Products and Technology

We have accumulated a portfolio of patent protected technologies and products for the identification of vulnerable plaque including IVUS, VH IVUS tissue characterization, IVUS palpography, and elastography. IVUS palpography and elastography involve measuring the strain of the lumen and the plaque respectively with ultrasound signals gained during different cardiac cycles. We have developed fully functional working devices for each of these technologies and have used them all in clinical studies. At this time, our focus is on our IVUS base of technologies to identify and risk stratify vulnerable plaque with other patient related information that is readily available. With our IVUS and FM technologies we have been able to clinically demonstrate that we can identify many of the characteristics and locations of vulnerable plaque. We are in the process of conducting numerous clinical studies to correlate vulnerable plaque to its clinical significance and risk.

#### Optical Coherence Tomography

In December 2007, we acquired CardioSpectra, Inc. Through CardioSpectra, we are developing innovative Optical Coherence Tomography (OCT) technology, which is expected to complement our existing product offerings and further enhance our position as an imaging technology leader in the field of interventional medicine. We believe this OCT technology and products will be an important addition to Volcano, as we expect that it will allow us to expand our reach into clinical situations where extremely high resolution imaging is paramount. Our long term goal is to integrate this OCT functionality directly into our s5i integrated imaging suite of products. Our OCT system allows fast, easy imaging of highly detailed structures in the vasculature, including vessel wall defects, intra-luminal thrombus and stent struts. The ability to visualize stent expansion and apposition is excellent when using OCT. CardioSpectra's OCT resolution is able to visualize even very thin layers of cells covering drug eluting stent struts at follow-up. We expect this capability will be highly valued by other device manufacturers as they design and conduct clinical trials to assess the safety and effectiveness of new implantable devices.

#### **IVUS** Guided Therapies

As more procedures move to percutaneous interventional approaches, there is an opportunity to integrate the imaging capability of IVUS with coronary and peripheral therapeutic devices. Many such devices have been developed and tested including IVUS guided chronic total occlusion re-entry devices, balloons, stents, and cell or drug delivery systems for angiogenesis, or the proliferation of blood vessels, and myogenesis, or the proliferation of heart tissue. We currently have a commercial relationship with Medtronic in which we provide them with IVUS imaging components that are incorporated onto their Pioneer chronic total occlusion re-entry device for peripheral artery applications. In addition, we are developing IVUS guided therapy products that, if commercialized, will further expand and differentiate our product offering, drive IVUS utilization and enable us to participate in large endovascular market opportunities, including the market for coronary and peripheral bare metal stents and balloons. IVUS can also be integrated with and guide leads for implantable cardiac rhythm management devices, percutaneous valves, abdominal aortic aneurysm grafts, plaque ablation or excision devices, inferior vena cava filters, and thrombectomy devices. Additionally, there are opportunities to extend the utility of the pressure and flow guide wires into different electrophysiology applications and structural heart disease assessments.

#### Intra-Cardiac Echocardiography

We have identified Intra-Cardiac Echocardiography, or ICE, as a field in which ultrasound can provide meaningful benefit to interventionalists performing certain intra-cardiac procedures. ICE is closely related to IVUS in terms of

both technology and markets. While IVUS utilizes ultrasound to provide images of the vessel wall from within the vasculature and guide intravascular procedures, ICE utilizes ultrasound to image and measure structures inside the chambers of the heart from within the heart or its major vessels, and guide intra-cardiac procedures performed by interventional cardiologists and by electrophysiologists. Important procedures where ICE is used to guide intervention include closure of septal wall defects, and mapping and ablation of cardiac arrhythmias.

#### **Clinical Program**

We have pursued a clinical development strategy of using FDA-cleared IVUS products to be at the forefront in demonstrating utility in markets into which we are attempting to increase penetration or which we intend to develop as new markets. These markets include stent placement and optimization, vulnerable plaque detection and therapy guidance in the coronary and carotid arteries. Our clinical studies are generally post-marketing studies conducted to provide data regarding diagnostic effectiveness and disease treatment outcomes. These studies often collect acute, procedural, safety and long-term efficacy data. They include randomized prospective studies, registries and single-center studies. The goal of our vulnerable plaque clinical program is to identify, risk assess, and guide percutaneous interventional and pharmacologic, or relating to the study of drugs, their sources, their nature and their properties, treatments of vulnerable plaque in the coronary and carotid arteries.

The following is a summary of our current ongoing and significant completed clinical studies:

Study	Indication	Study Design	Status	Collaborator(s)
ADAPT (US/Europe)	Study of the optimal placement of drug eluting stents and optimal anti-platelet therapy	11,000 patient, multi-center study of drug- eluting stent placement and stent thrombosis with a 3,000 patient IVUS sub-study	Enrollment to begin in March 2008	Cardiovascular Research Foundation (CRF), Abbott Vascular, Boston Scientific and Johnson & Johnson
PROSPECT (US/Europe)	Natural history study of plaque to investigate non-flow obstructing lesions with an increased risk for future coronary events	700 patient, multi- center study of acute coronary syndrome patients with single or double CAD; non- randomized	Enrollment completed, follow up ongoing; interim baseline data from the first 250 patients was presented in October 2006	Abbott Vascular
Volcano VH Registry (Worldwide)	Study of correlation of coronary plaque characteristics with patient demographics, clinical presentation and cardiac risk factors	3,000 patient, non- randomized prospective, multi- center, global, registry imaging study	Enrollment completed, analysis of data in progress; interim data on first 990 patients presented in October 2006; publications planned for 2H 2007	_
IBIS-2 (Europe)	Estimate the effect on the novel GSK Lp-PLA(2) inhibitor on circulatory biomarkers and coronary plaque biomechanical properties as well as endothelial dysfunction, coronary plaque volume and composition with IVUS grayscale palpography and VH IVUS	330 patient, randomized, placebo-controlled, parallel-group, one year treatment study	Enrollment completed, one year follow up completed; presentation of data expected 1H 2008	GlaxoSmithKline .
CAPITAL (US)	Evaluate the prevalence and correlation of the data provided by IVUS grayscale and VH IVUS, such as plaque components, quantities, configurations and location, to patient demographics, clinical presentation and risk factors for carotid artery disease	30 patient, single- center study	Enrollment completed; analysis of data completed and published	Arizona Heart Institute

#### Assessment of Dual Anti-Platelet Therapy with Drug-Eluting Stents (ADAPT)

We are sponsoring the first major study designed to examine the role of IVUS in ensuring accurate stent placement. The 3,000 patient IVUS sub-study is part of the Cardiovascular Research Foundation's (CRF) ADAPT-DES study a prospective, multi-center registry of 11,000 (and up to 15,000) patients with coronary artery disease undergoing stent-assisted percutaneous coronary intervention (PCI) using drug-eluting stents (DES). The study's main objectives are to determine the frequency, timing and correlates (clinical, angiographic and IVUS) of DES thrombosis and the relationship of aspirin and/or clopidogrel hyporesponsiveness, and general platelet reactivity to early and late DES thrombosis. The ADAPT-DES IVUS sub-study is expected to provide definitive evidence as to whether IVUS can identify patients at heightened risk for stent thrombosis. Volcano's Eagle Eye® Gold IVUS catheters will be used in all sub-study patients at the initiation of the sub-study and in follow-up assessments. Analysis will include assessment of lesion morphology by using both traditional grayscale IVUS and Volcano's proprietary VH<sup>TM</sup> IVUS tissue characterization technology.

#### Providing Regional Observations to Study Predictors of Events in the Coronary Tree (PROSPECT)

PROSPECT, sponsored by Abbott Vascular and us, is a natural history study of plaque. The purpose of the multicenter imaging study of patients with unstable atherosclerotic lesions, is to identify imaging modalities or blood markers of inflammation that indicate which non-flow limiting lesions are at higher risk for future acute coronary events. Approximately 700 ACS patients in the United States and Europe with single or double vessel CAD have been enrolled and will be followed for up to five years. In addition to angiography, IVUS grayscale, VH IVUS tissue characterization, IVUS palpography involving a sub-group only and biomarkers will be utilized to explore the relationship between observations of these modalities and subsequent cardiac events. To establish a baseline, IVUS imaging were performed on all three major coronary arteries and biochemical features that can be used to measure the progress of disease or the effects of treatment, or biomarkers, will be assessed. In the event of a major adverse cardiac event, or MACE, such as cardiac death, cardiac arrest, re-hospitalization for angina, myocardial infarction, or revascularization by PCI or coronary artery bypass graft, or CABG, patients will be re-imaged in both the vessel in which the lesion causing the event occurred and in non-affected vessels. Event rates are determined on the date that the patient is in the hospital and then after 30 days, 180 days, one year and yearly thereafter for up to five years. This study is designed to prove that our IVUS technology is predictive, and can identify those plaques that are vulnerable and may cause coronary events. The study commenced enrollment in January 2005.

As of December 31, 2007, there were 700 patients enrolled in the study and patients are being followed up per the protocol. Interim baseline data from the first 250 patients was presented in October 2006. The interim data indicated that three-vessel VH IVUS imaging is feasible in a clinical setting. The interim data also indicated an average of 2.5 angiographically visible but "mild" lesions per patient are left untreated, and that 16% of these lesions are in fact "severe" by quantitative coronary angiography. "Mild" lesions are those with a diameter stenosis of less than 30% and "severe" lesions are those with a diameter stenosis of greater than 50%. By IVUS, the total number of identified lesions, on average, was 2.9 per patient in the proximal and mid coronary tree, of which 25% are classified as severe by IVUS. Severe by IVUS is defined as vessel area less than 4mm2 and greater than 40% plaque burden in the artery at the location of the lesion. VH IVUS was able to identify lesions with presumed characteristics of vulnerable plaque in 35% of patients. Those patients remain untreated as part of the PROSPECT trial design. These plaques were identified by VH IVUS as thin cap fibro-atheromas.

#### Volcano VH Registry

We sponsor a VH Registry, an *in vivo* study of the prevalence of atherosclerosis and its plaque components in the coronary arteries. The purpose of the registry is to allow researchers to understand the correlation of data provided by IVUS and our VH IVUS functionality, such as plaque components, quantities, configuration and location, to patient demographics, clinical presentation and cardiac risk factors. The registry is a prospective, global multicenter, non-randomized, all-comer study of approximately 3,000 PCI patients in the United States, Europe and Japan. Each participant will undergo IVUS imaging of coronary arteries to be stented and will be eligible to undergo IVUS imaging of the same arteries should such participant experience a subsequent cardiac event that requires catheterization. This allows comparison of the initial and follow-up data to begin to draw observations on correlations between the initial images and plaque progression or clinical events. This study will ascertain the

prevalence of non-flow obstructing lesions by tissue characteristics, but not the clinical significance, in an attempt to provide a broader view of the prevalence of disease characteristics in the ACS population as well as the broader PCI population. The study commenced enrollment in March 2004.

As of December 31, 2007, there were 3,225 patients enrolled in the study and enrollment is complete. Patients are being observed pursuant to the protocol. Interim data presented in October 2006 indicated several preliminary findings from the first 990 patients. The interim data indicated that increased amounts of calcium and necrotic core are associated with prior cardiac history, myocardial infarction, previous coronary bypass and diabetes; patients with ischemia do have an increased plaque burden and also a difference in composition of their plaque; and that a combination of aspirin and statin therapy correlated with less plaque burden, and less fibrous and fibro-fatty plaque, suggesting the effectiveness of systemic therapy may be measured by both amount and composition of plaque. In addition, initial data also demonstrated gender specific characteristics in plaque morphology. The ability to correlate demographic data with plaque characteristics in combination with other studies will allow us to clinically identify and treat high-risk lesions that are currently not diagnosed.

#### Study of Prospective Events in Coronary Intermediate Atherosclerotic Lesions (SPECIAL)

SPECIAL, sponsored by Goodman, Fukuda Denshi and us, is a natural history study of vulnerable plaque with invasive imaging follow-up of a portion of the patients enrolled regardless of whether they have a clinical event or not. The purpose of the study is to identify imaging modalities and/or blood markers of inflammation which may aid in the identification of vulnerable plaque which increases risk of future acute coronary events in ACS patients. We will enroll up to 1,000 ACS patients with single or double vessel CAD at approximately 100 centers in Japan, with half randomized into an IVUS arm and half into a non-IVUS arm. Patients in the IVUS arm will be imaged with angiography and IVUS and these images supplemented by VH IVUS tissue characterization and biomarkers. Patients in the non-IVUS arm will be imaged with angiography alone. In the event of a MACE, patients will be reimaged with the technology they were imaged with at baseline. Additionally, all patients will be imaged 12 months after the original procedure with the same technology they were imaged with at baseline. The two primary endpoints of the study are the MACE associated with progression of plaque during a 12-month period and the progression of plaque as measured by angiography and our VH IVUS functionality 12 months after intervention. SPECIAL is designed to validate the clinical significance of vulnerable plaque and provide additional information on silent plaque progression which can lead to clinical events. Study enrollment commenced in April 2006. Enrollment is projected to be completed by mid-2008, and the last 12-month invasive follow-up is projected to be completed by the end of 2009.

#### Integrated Biomarker and Imaging Study (IBIS-2)

IBIS-2, sponsored by GSK and us, is an international, multi-center, randomized, placebo-controlled, parallel-group, one year treatment study in approximately 330 ACS and non-ACS subjects with angiographically documented CAD. The study is designed to compare the effects of an Lp-PLA(2) inhibitor to placebo following 52 weeks of once daily blinded treatment. The study will estimate the effect of GSK's Lp-PLA(2) inhibitor on circulatory biomarkers and coronary plaque biomechanical properties, as well as dysfunction of the endothelium, the layer of thin, flat cells that lines the interior surface of blood vessels, coronary plaque volume and composition using IVUS, VH IVUS functionality and palpography. A follow-up catheterization was performed on all subjects a year after baseline. The follow-up included all IVUS-based imaging and angiography of the non-intervened artery. IBIS-2 is the first study to look at the effect of a drug therapy on certain plaque characteristics as measured by our grayscale IVUS, VH IVUS and IVUS palpography as compared to a placebo therapy. The study started enrollment in November 2005. We completed enrollment of 330 patients in August 2006. Patients are being followed up per the protocol.

#### Carotid Artery Plaque Virtual Histology Evaluation (CAPITAL)

CAPITAL, sponsored by the Arizona Heart Institute and us, is the first study to assess VH IVUS data, both quantitative and qualitative, of plaque components in carotid arteries prior to carotid endarterectomy, the incision of the atherosclerotic plaque from the carotid artery or CEA, and carotid artery stenting, or CAS, procedures. The purpose of this single center study is to evaluate the prevalence and correlation of data provided by IVUS and our

VH IVUS functionality, such as plaque components, quantities, configurations and location, to patient demographics, clinical presentation and risk factors for carotid artery disease. The study enrolled 30 patients, half CEA and half CAS patients, and enrolled patients must be symptomatic with lesions at least 50% stenosed or asymptomatic with lesions at least 75% stenosed in at least one carotid artery. For the CEA procedures, VH IVUS data has been validated to histological findings from the surgically removed plaque. For the CAS procedures, VH IVUS data was correlated with the presence, type, quantity and size of captured embolic material during the CAS procedure. This study ascertained the prevalence of non-flow obstructing lesions by tissue characteristics rather than clinical significance. The study started enrollment in January 2006. Enrollment was completed and the data was analyzed. Our phased array IVUS catheters, which are being used in CAPITAL, are FDA-cleared for peripheral applications, which include the carotid arteries.

The carotid arteries are one of the most common sites of peripheral vascular disease. CAS procedures are currently FDA-approved for a subset of these procedures, those that are performed on patients who are symptomatic and show at least 70% stenosis. However, most people who are at risk for ischemic strokes will not undergo a CAS procedure. We believe that endovascular techniques that have been developed to avoid open surgery and are in early stages of adoption, and CAS procedures using devices such as stents, embolic protection systems and IVUS, will significantly expand the addressable patient population to include all people who are at risk for ischemic stroke and not just those patients who are symptomatic and have 70% stenosis.

#### Clinical Studies Using IVUS and VH Products

We are or have been involved with GSK, Novartis AG, Lipid Sciences, Inc., Tanabe Seiyaku Co., Ltd. and Kowa Company, Ltd. on clinical studies using IVUS and our VH IVUS product. We believe the additional information our VH IVUS product and IVUS palpography provides will enable us to participate in a growing number of drug studies.

#### Sales, Marketing and Distribution

We have direct sales capability in the United States, Western Europe and Japan. We intend to continue to increase our direct sales personnel. In addition to our direct sales efforts, we have Japanese distribution relationships with Goodman, Fukuda Denshi and Johnson & Johnson Cordis Division. Altogether, we have 50 distribution relationships in 40 countries.

Property and equipment includes certain medical diagnostic equipment that is located at customer premises. This equipment is placed at our discretion with certain customers, such as key opinion leaders and other strategic customers who agree to use the equipment and purchase specified quantities of our single-procedure disposable products. We retain the ownership of the equipment and have the right to remove the equipment if it is not being utilized according to expectations. Depreciation expense relating to this equipment of \$1.8 million, \$1.8 million and \$1.4 million is recorded in cost of revenues during the years ended December 31, 2007, 2006 and 2005, respectively. The net book value of this equipment was \$4.8 million and \$2.1 million at December 31, 2007 and December 31, 2006, respectively. Also included in medical diagnostic equipment is property and equipment used for demonstration and evaluation purposes. Depreciation expense for equipment used for demonstration and evaluation purposes is recorded in selling, general and administrative expenses. Depreciation expense relating to this equipment of \$793,000, \$515,000 and \$335,000 is recorded in selling, general and administrative expenses during the years ended December 31, 2007, 2006 and 2005, respectively. The net book value of this equipment was \$2.9 million and \$1.0 million at December 31, 2007 and December 31, 2006, respectively. Medical diagnostic equipment is recorded at our cost to acquire or manufacture the equipment and is depreciated over the estimated useful life (generally three to five years).

We have entered into a supply and distribution agreement with GE that forms an important part of our sales and marketing strategy. GE has a significant share of the worldwide cath lab installation market and competes both for a substantial number of new cath lab installations as well as existing cath lab upgrades. We will leverage GE's sales force to market our s5i GE Innova IVUS consoles on a global basis, excluding Japan.

We plan to enter into additional agreements to market integrated systems. These agreements allow us to coordinate our marketing efforts with our strategic partners while still dealing directly with the customer.

We sell consoles and disposables, including IVUS catheters and FM guide wires, using different approaches:

- Consoles. We sell our consoles through our own direct sales force, through distributors and through our supply and distribution agreement with GE.
- **Disposables.** We leverage our installed base of consoles to drive recurring sales of our proprietary disposables. We provide training and clinical support to users of our products to increase their familiarity with product features and benefits, and thereby increase usage.

Our relationships with physician thought leaders in interventional cardiology are an important component of our selling efforts. These relationships are typically built around research collaborations that enable us to better understand and articulate the most useful features and benefits of our products, and to develop new solutions to challenges in percutaneous interventional medicine.

As of December 31, 2007, our global marketing team was comprised of 23 individuals, covering product management, corporate communications and programs, clinical support, and education and training. We devote significant resources to training and educating physicians in the use and benefits of our products. We also promote our products through medical society meetings attended by interventionalists.

#### **United States**

In the United States, we sell our products directly to customers and through GE, our distributor. As of December 31, 2007, we had 98 direct sales professionals focused on selling both our IVUS and FM products. Our U.S. sales organization includes 36 account sales representatives, 52 clinical consultants and 10 sales administration personnel. Account sales representatives are responsible for selling our products while the clinical consultants work with customers on training and supporting product use. We currently have 8 regions headed by a regional manager in each region and two Vice Presidents of U.S. Sales.

#### International

We derive, and anticipate we will continue to derive, a significant portion of our revenues from operations in Japan and Europe. Any material decrease in our international revenues or inability to expand our international operations would adversely impact our revenues, results of operations and financial condition. Our international operations expose us and our representatives, agents and distributors to risks inherent in operating in foreign jurisdictions, including the risks described in "Risk Factors—The risks inherent in our international operations may adversely impact our revenues, results of operations and financial condition."

#### Japan

Three companies distribute our IVUS and FM products in Japan. We have direct contractual relationships with Goodman, Fukuda Denshi and Johnson & Johnson Cordis Division. In addition, Fukuda Denshi has sub-distribution agreements with other parties. While these multi-level relationships allow us to access specific customers and markets, they create complex distribution arrangements and increase our reliance on our Japanese distributors.

We currently support our Japanese distributors through our Tokyo-based subsidiary, Volcano Japan Co., Ltd. (Volcano Japan). As of December 31, 2007, Volcano Japan had a General Manager and 11 sales and support staff. Until June 1, 2006, our Japanese distributors handled all matters relating to importation, warehousing and regulatory compliance for our products in Japan. With respect to our phased array IVUS products, Volcano Japan now controls these matters due to the transfer by Fukuda Denshi of the Japanese regulatory approvals, or shonins, related to these products. This transfer took place on June 1, 2006. As a result of the transfer of the shonins, we have retained a third party to assist with the additional responsibilities related to importation and warehousing. Our distribution agreements in Japan are generally organized according to specific clinical markets:

#### Interventional Cardiology

Goodman distributes our IVUS products for use in interventional cardiology to over 900 Japanese accounts. In addition, Fukuda Denshi distributes our IVUS products to approximately 150 additional interventional cardiology

accounts in Japan. Until June 1, 2006, Fukuda Denshi was responsible for obtaining and maintaining the shonins related to our IVUS products. Our previous agreements with Fukuda Denshi were scheduled to terminate in 2007. However, we entered into an agreement with Fukuda Denshi in March 2006 which became effective upon the transfer to us of the shonins related to our IVUS products. Such transfer took place on June 1, 2006. Upon the effectiveness of the agreement with Fukuda Denshi, our distribution relationship with Fukuda Denshi was extended until 2012 and our other previous agreements with Fukuda Denshi were terminated. As a result of the transfer of the shonins, Volcano Japan has assumed the regulatory responsibilities related to such products.

#### Functional Measurement

Goodman currently distributes our FM products in Japan to all customers. In addition, Goodman is responsible for Japanese regulatory compliance relating to our FM products.

#### Endovascular/ Peripheral Applications

Johnson & Johnson Cordis Division distributes our IVUS disposable products in Japan for use in endovascular and peripheral applications. Our current contractual arrangements allow us to engage other third parties to distribute our IVUS products in Japan for this market.

#### Europe

We distribute our IVUS and FM products in Europe through our subsidiary, Volcano Europe, S.A./N.V. (Volcano Europe). We sell our products directly to customers in certain European markets and utilize distributors in other European markets, including Spain, Portugal and parts of Italy. As of December 31, 2007, our distribution efforts in Europe were led by a General Manager, a Director of European Sales, 13 account representatives and seven clinical specialists.

#### Other International

In emerging markets with rapid growth in interventional procedures, including in the major markets of Asia Pacific, excluding Japan, Latin America, Europe, Australia, Africa and the Middle East, we have distributor relationships through which we sell our products. Our distributors are involved in product launch planning, education and training, physician support and clinical trial management.

#### Financial Information About Geographic Areas

The following table sets forth our revenues by geography expressed as dollar amounts (in thousands) and as a percentage of revenue by geography to total revenue:

	2007	Percent of Total Revenue	2006	Percent of Total Revenue	2005	Percent of Total Revenue
Revenues:						
United States	\$ 66,411	50.8%	\$ 51,013	49.5%	\$ 40,933	44.5%
Japan	35,186	26.9	30,082	29.2	33,207	36.1
Europe, the Middle East and Africa	23,995	18.4	17,765	17.2	15,294	16.6
Rest of world	 5,022	3.8	 4,188	4.1	2,466	2.7
,	\$ 130,614	100.0	\$ 103,048	100.0	\$ 91,900	100.0

#### Supply and Distribution Agreement with GE

In March 2006, we entered into a supply and distribution agreement with GE, pursuant to which we are collaborating on the development and distribution of our s5i GE Innova IVUS product, which is our IVUS imaging system console that is installed directly into a cath lab on a permanent basis and is able to be integrated with GE's Innova System. Integration with GE's Innova System allows control of the IVUS system from cath lab control

stations located at the patient table and in the cath lab control room. Under the terms of the agreement, GE has been granted exclusive distribution rights worldwide, excluding Japan, for the s5i GE Innova IVUS product for a period of 12 months, subject to minimum purchase forecasts. The 12-month exclusivity period ended on August 15, 2007, after which, GE had non-exclusive distribution rights for the s5i GE Innova IVUS product. In addition, GE has been granted non-exclusive distribution rights worldwide, excluding Japan, for our s5i product. GE is responsible for various items relating to the integration of the s5i GE Innova IVUS product into its Innova system, including offering the products as part of its cardiovascular and interventional radiology product lines. Unless extended, or terminated earlier in accordance with its terms, the agreement will expire on December 31, 2009.

#### Competition

We compete primarily on the basis of our ability to assist in the diagnosis and treatment of vascular diseases safely and effectively, with ease and predictability of product use, adequate third-party reimbursement, brand name recognition and cost. We believe that we compete favorably with respect to these factors, although there can be no assurance that we will be able to continue to do so in the future or that new products that perform better than those we offer will not be introduced. We believe that our continued success depends on our ability to:

- · innovate and maintain scientifically advanced technology;
- apply our technology across products and markets;
- · develop proprietary products;
- successfully conduct clinical studies that expand our markets;
- · obtain and maintain patent protection for our products;
- · obtain and maintain regulatory approvals;
- · cost-effectively manufacture and successfully market our products; and
- attract and retain skilled personnel.

Our markets are highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Many of our competitors have significantly greater financial and human resources than we do and have established relationships with healthcare professionals, customers and third-party payors. In addition many of our competitors have established distributor networks, greater resources for product development, sales and marketing, additional lines of products and the ability to offer rebates or bundle products to offer discounts or incentives. Our primary IVUS competitor globally is Boston Scientific, but we also compete with Terumo Corporation in Japan. In the FM market, our primary competitor is Radi Medical Systems AB, a private medical device manufacturer. Because of the size of the vascular market opportunities, competitors and potential competitors have dedicated and will continue to dedicate significant resources to aggressively promote their products. New product developments that could compete with us more effectively are likely because the vascular disease market is characterized by extensive research efforts and technological progress. Competitors may develop technologies and products that are safer, more effective, easier to use or less expensive than ours.

We have encountered and expect to continue to encounter potential physician customers who, due to existing relationships with our competitors, are committed to or prefer the products offered by these competitors. We expect that competitive pressures may result in price reductions and reduced margins over time for our products. Our products may be rendered obsolete or uneconomical by technological advances developed by one or more of our competitors.

#### **Intellectual Property**

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain the proprietary aspects of our technologies. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to aggressively protect our intellectual property.

We require our employees and consultants to execute confidentiality agreements in connection with their employment or consulting relationships with us. We also require our employees and consultants who work on our products to agree to disclose and assign to us all inventions conceived during the term of their employment, while using our property or which relate to our business. Despite measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary. In addition, our competitors may independently develop similar technologies.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. As the number of entrants into our market increases, the risk of an infringement claim against us grows. While we attempt to ensure that our products and methods do not infringe other parties' patents and proprietary rights, our competitors may assert that our products, and the methods we employ, are covered by patents held by them. In addition, our competitors may assert that future products and methods we may employ infringe their patents. If third parties claim that we infringe upon their intellectual property rights, we may incur liabilities and costs and may have to redesign or discontinue selling the affected product. Risks to our intellectual property rights are listed in "Risk Factors—Risks Related to Our Intellectual Property and Potential Litigation."

#### Patents and Trademarks

As of December 31, 2007, we had at least 191 owned or licensed U.S. and international patents and 154 owned or licensed U.S. and international patent applications. We intend to continue to expand our intellectual property position to protect the design and use of our products, principally in the areas of IVUS and FM for the diagnosis and guidance of treatment of vascular and structural heart disease. Additionally, we utilize trademarks, trade names or logos in conjunction with the sale of our products. We currently have registered trademarks for, at least, Volcano®, Eagle Eye®, Visions®, Revolution®, ComboWire®, SmartMap®, ComboMap®, SmartWire®, FloWire®, WaveWire®, VH®, Trak Back®, FloMap®, ChromaFlo® and Avanar®, and are in the process of registering certain other of our trademarks with the U.S. Patent and Trademark Office including, but not limited to, vfusion powered by Volcano<sup>TM</sup>, vfusion<sup>TM</sup>, AIM<sup>TM</sup>, Safe and Sound<sup>TM</sup> and SpinVision<sup>TM</sup>. We continue to invest in internal research and development of concepts within our current markets and within other potential future markets. This enables us to continue to build our patent portfolio in areas of company interest.

#### Third-party Licenses

We have expanded our product portfolio by both in-licensing and out-licensing technology and intellectual property.

#### The Cleveland Clinic License

In April 2002, we entered into a license agreement with The Cleveland Clinic Foundation. The incorporation of our VH IVUS functionality into our IVUS product offerings depends on access to patents owned by The Cleveland Clinic Foundation and made available to us pursuant to an exclusive, irrevocable, in-bound license granted to us by The Cleveland Clinic Foundation pursuant to the license agreement. These worldwide license rights are within the field of diagnosis and treatment of atherosclerosis and related vascular diseases using intravascular methods and include the right to sublicense. We commercially launched our VH IVUS functionality for our IVUS products in 2005. In relation to the sale of our products which incorporate any of the licensed patents, we will be responsible for paying certain royalties to The Cleveland Clinic Foundation. These royalties vary depending on where our product is sold, how the patent is incorporated into our product and when in the period of patent protection our product is sold. This license granted under this agreement terminates on a country-by-country basis upon the expiration of the last to expire patent licensed under the agreement. However, the agreement will continue in effect as long as we continue to incorporate into our products the technology licensed to us by The Cleveland Clinic Foundation.

#### Asset Transfer Agreement with Philips

In 2003, we entered into an asset transfer agreement with Philips whereby Philips transferred to us rights to certain intellectual property that is related to IVUS and is owned by Boston Scientific. Boston Scientific was required to

make these patents and related intellectual property available to third parties based on action by the Federal Trade Commission and the United States District Court. We obtained rights through our wholly-owned subsidiary, Pacific Rim Medical Ventures, which merged into us on December 30, 2004. In addition to certain upfront and annual payments, we must pay Philips royalties based on the volume of products sold by us that incorporate technology acquired pursuant to the asset transfer agreement. This intellectual property in conjunction with the intellectual property that we acquired from Jomed, Inc. in 2003 and the intellectual property we have developed form the foundation of our IVUS products.

#### License with Medtronic

Concurrent with our acquisition of the IVUS and FM product lines from Jomed, Inc. in July 2003, we granted to Medtronic a fully paid, royalty free, worldwide, exclusive license to certain of our patents for a specific field. The field allows the inclusion of our IVUS imaging components into Medtronic's Pioneer product. This product is also being used in clinical studies by Medtronic in collaboration with Genzyme Corporation for delivery of cells to the myocardium in an attempt to create viable myocardium.

#### Research and Development

Our research efforts are directed towards the development of new products and technologies that expand our existing platform of capabilities and applications in support of percutaneous interventions. As of December 31, 2007, our research and development staff consisted of 90 full-time engineers and technicians. The majority of this staff is located in Rancho Cordova, California. We also have research and development staff in Cleveland, Ohio and San Antonio, Texas. Our research and development staff are focused on the development of new IVUS systems and catheters, FM consoles and guide wires, image-guided therapy systems, Optical Coherence Tomography and advanced clinical applications that support our core business objectives.

Our product development process incorporates teams organized around each of our core technologies, with each team having representatives from research and development, marketing, regulatory, quality, clinical affairs and manufacturing. Consultants are utilized when additional specialized expertise is required. Our team sets development priorities based on communicated customer needs. The feedback received from beta testing is incorporated into successive design iterations until a new product is ready for release.

Our research and development expenses were \$20.3 million in 2007, \$16.9 million in 2006 and \$15.1 million in 2005. These totals include the research and development, clinical and regulatory affairs department expenses. In addition, in 2007 we incurred in-process research and development expense of \$26.2 million related to our December 2007 acquisition of CardioSpectra.

#### Manufacturing

Our manufacturing facility is located in Rancho Cordova, California, where we produce IVUS consoles, FM consoles, IVUS catheters and FM guide wires. Our manufacturing strategy for our consoles is to use third-party manufacturing partners to produce circuit boards and mechanical sub-assemblies. We perform incoming inspection, final assembly and test of products to assure quality control. Our manufacturing strategy for the single-procedure disposable products is to use third-party manufacturing partners for certain proprietary components. We perform incoming inspection on these components, assemble them into finished devices and test the final product to assure quality control. A portion of the assembly is performed at third party contractor using automated assembly processes and equipment, we are dependent on the third party for its day-to-day control and protection of the system. We conduct the remaining process operations including final testing on the scanner in the Rancho Cordova facility.

We manufacture our products in a controlled environment and have implemented quality control systems as part of our manufacturing processes. The control systems materially comply with the United States FDA Quality System Regulations, or QSR. We believe we are in material compliance with the FDA QSR for medical devices, with ISO 13485 quality standards, and with applicable medical device directives promulgated by the European Union, and policy on the Canadian Medical Devices Conformity Assessment System, which facilitates entry of our products

into the European Union and Canada. The FDA and E.U. Notified Body have both inspected our manufacturing facilities in the last 20 months.

Our current facility has been inspected by the FDA, the California Department of Health Services Food and Drug Branch, and the E.U. Notified Body. Observations for improvements were noted as well as findings of deficiencies. We believe we have adequately addressed the inspectional observations and we are in material compliance with applicable regulatory directives. We expect to be inspected by the FDA and state and international authorities again in the future. If the FDA or state or international authorities find significant shortcomings, we could be subject to fines, recalls or requirements to halt manufacturing and shipments of affected products. Any of these enforcement actions could have a material effect on our business, by disrupting our ability to manufacture and sell product, impacting our profitability or harming our reputation or that of our products. See "Risk Factors—Risks Related to Government Regulation."

#### **Government Regulation**

Our products are medical devices subject to extensive and rigorous regulation by the FDA, as well as other Federal and state regulatory bodies in the United States and comparable authorities in other countries. We currently market our products in the United States under pre-market notification, or 510(k), clearance. If we seek to market new products, or to market new indications for our existing products, we will be required to file for and obtain 510(k) clearance or pre-market approval, or PMA.

The FDA regulations govern the following activities that we perform, or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

- product design, development and manufacture;
- · product safety, testing, labeling and storage;
- · pre-marketing clearance or approval;
- · record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths or serious injuries and repair or recall of products.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- · warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or PMA approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or PMA approvals that have already been granted; and
- criminal prosecution.

#### **Employees**

As of December 31, 2007, we had 639 employees. None of our employees is represented by a labor union, and we believe our employee relations are good.

#### Seasonality

Our business is generally seasonal in nature. Historically, demand for our products has been the highest in the fourth quarter. We traditionally experience lower sales volumes in the third quarter than throughout the rest of the year as a result of the holiday schedule during the summer months. Our working capital requirements vary from period to period depending on manufacturing volumes, the timing of deliveries and the payment cycles of our customers.

#### **Corporate Information**

We were incorporated in the state of Delaware in January 2000 and until 2003 were a development stage company substantially devoted to the research and development of tools designed to diagnose vulnerable plaque. In July 2003, we acquired substantially all of the assets related to the IVUS and FM product lines from Jomed, Inc. and commenced the manufacturing, sale and distribution of IVUS and FM products.

#### **Available Information**

Our corporate website is www.volcanocorp.com and our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding the company, at www.sec.gov. These reports and other information concerning the company may also be accessed at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The contents of these websites are not incorporated into this filing. Further, our reference to the URLs for these websites are intended to be inactive textual references only.

#### Item 1A. Risk Factors

#### Risks Related to Our Business and Industry

We are dependent on the success of our IVUS consoles and catheters and cannot be certain that our products will achieve the broad acceptance necessary to develop a sustainable, profitable business.

Our revenues are primarily derived from sales of our intravascular ultrasound, or IVUS, products, which include our consoles and our single-procedure disposable catheters. We expect that sales of our IVUS products will continue to account for substantially all of our revenues for the foreseeable future. IVUS technology is widely used for determining the placement of stents in patients with coronary disease in Japan, where we believe, based on internal estimates, the procedure penetration rate was over 60% in 2007. By contrast, the penetration rate in the United States for the same type of procedure was approximately 12% in 2007. It is difficult to predict the penetration and future growth rate or size of the market for IVUS technology. The expansion of the IVUS market depends on a number of factors, such as:

- physicians accepting the benefits of the use of IVUS in conjunction with angiography;
- physician experience with IVUS products;
- the availability of, and physicians' willingness to participate in, training required to gain proficiency in the
  use of IVUS products;
- · the additional procedure time required for use of IVUS;
- perceived risks generally associated with the use of new products and procedures;
- the availability of alternative treatments or procedures that are perceived to be or are more effective, safer, easier to use or less costly than IVUS technology;
- · availability of adequate reimbursement; and

marketing efforts and publicity regarding IVUS technology.

Even if IVUS technology gains wide market acceptance, our IVUS products may not adequately address market requirements and may not continue to gain market acceptance among physicians, healthcare payors and the medical community due to factors such as:

- the lack of perceived benefits of information on plaque composition available to the physician through use of our IVUS products, including the ability to identify calcified and other forms of plaque;
- the actual and perceived ease of use of our IVUS products;
- the quality of the images rendered by our IVUS products;
- the cost, performance, benefits and reliability of our IVUS products relative to the products and services offered by our competitors;
- · the lack of perceived benefit of integration of our IVUS products into the cath lab; and
- · the extent and timing of technological advances.

If IVUS technology generally, or our IVUS products specifically, do not gain wide market acceptance, we may not be able to achieve our anticipated growth, revenues or profitability and our results of operations would suffer.

### We have a limited operating history, have incurred significant operating losses since inception and cannot assure you that we will achieve profitability.

We were formed in January 2000 and until 2003 were a development stage company substantially devoted to the research and development of tools designed to diagnose vulnerable plaque. In July 2003, we acquired substantially all of the assets related to the IVUS and functional measurement, or FM, product lines from Jomed, Inc., or the Jomed Acquisition, and commenced the manufacturing, sale and distribution of IVUS and FM products. We have yet to demonstrate that we have sufficient revenues to become a sustainable, profitable business. Even if we do achieve significant revenues, we expect our operating expenses will increase as we expand our business to meet anticipated growing demand for our products and as we devote resources to our sales, marketing and research and development activities. If we are unable to reduce our cost of revenues and our operating expenses, we may not achieve profitability. As of December 31, 2007, we had an accumulated deficit of \$90.6 million. We expect to experience quarterly fluctuations in our revenues due to the timing of capital purchases by our customers and to a lesser degree the seasonality of disposable consumption by our customers and our expenses as we make future investments in research and development, selling and marketing and general and administrative activities that will cause us to experience variability in our reported earnings and losses in future periods. Failure to achieve and sustain profitability would negatively impact the market price of our common stock.

#### If the clinical studies that we sponsor or co-sponsor are unsuccessful, or clinical data from studies conducted by other industry participants are negative, we may not be able to develop or increase penetration in identified markets and our business prospects may suffer.

We sponsor or co-sponsor several clinical studies to demonstrate the benefits of our products in current markets where we are trying to increase use of our products and in new markets. Implementing a study is time consuming and expensive, and the outcome is uncertain. The completion of any of these studies may be delayed or halted for numerous reasons, including, but not limited to, the following:

- the U.S. Food and Drug Administration, or the FDA, institutional review boards or other regulatory authorities do not approve a clinical study protocol or place a clinical study on hold;
- patients do not enroll in a clinical study or are not followed-up at the expected rate;
- patients experience adverse side effects, including adverse side effects to our or a co-sponsor's drug candidate or device;
- patients die during a clinical study for a variety of reasons that may or may not be related to our products, including the advanced stage of their disease and medical problems;

- third-party clinical investigators do not perform the clinical studies on the anticipated schedule or
  consistent with the clinical study protocol and good clinical practices, or other third-party organizations
  do not perform data collection and analysis in a timely or accurate manner;
- · our co-sponsors do not perform their obligations in relation to the clinical study or terminate the study;
- regulatory inspections of manufacturing facilities, which may, among other things, require us or a cosponsor to undertake corrective action or suspend the clinical studies;
- · changes in governmental regulations or administrative actions; and
- the interim results of the clinical study are inconclusive or negative; and the study design, although approved and completed, is inadequate to demonstrate safety and efficacy.

Some of the studies that we co-sponsor are designed to study the efficacy of a third-party's drug candidate or device. Such studies are designed and controlled by the third-party and the results of such studies will largely depend upon the success of the third-party's drug candidate or device. These studies may be terminated before completion for reasons beyond our control such as adverse events associated with a third-party drug candidate or device. A failure in such a study may have an adverse impact on our business by either the attribution of the study's failure to our technology or our inability to leverage publicity for proper functionality of our products as part of a failed study.

Clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. For example, our Volcano VH Registry has enrolled over 3,225 patients, the ADAPT study has a projected enrollment of 11,000 patients, PROSPECT has enrolled 700 patients and SPECIAL has a projected enrollment of 1,000 patients. Patient enrollment in clinical studies and completion of patient follow-up depend on many factors, including the size of the patient population, the study protocol, the proximity of patients to clinical sites, eligibility criteria for the study and patient compliance. For example, patients may be discouraged from enrolling in our clinical studies if the applicable protocol requires them to undergo extensive post-treatment procedures or if they are persuaded to participate in different contemporaneous studies conducted by other parties. Delays in patient enrollment or failure of patients to continue to participate in a study may result in an increase in costs, delays or the failure of the study. Such events may have a negative impact on our business by making it difficult to penetrate or expand certain identified markets. Further, if we are forced to contribute greater financial and clinical resources to a study, valuable resources will be diverted from other areas of our business.

Negative results from clinical studies conducted by other industry participants could harm our results. For example, recently the number of PCI procedures declined due to concerns attributed to late stent thrombosis and the long-term efficacy of drug-eluting stents. If the number of PCI procedures declines, the need for IVUS procedures could also decline and our business prospects may suffer.

If we are unable to identify the plaque that is most likely to rupture and cause a coronary event we may not be able to develop a market for our vulnerable plaque products or expand the market for existing products.

We are utilizing substantial resources toward developing technologies to aid in the identification, diagnosis and treatment of the plaque that is most likely to rupture and cause a coronary event, or vulnerable plaque. To date, a connection between ruptured plaque and coronary events has been shown in post-mortem studies, hypothetical models and certain statistical analyses. However, no technology has been proven in clinical trials to identify, prior to the occurrence of a coronary event, the plaque that is most likely to rupture and cause such an event. If we are unable to develop products or technologies that can identify which plaques are likely to rupture and cause a coronary event, a market for products to identify vulnerable plaque may not materialize and our business may suffer.

If sponsorship of the PROSPECT study is delayed or stopped, our ongoing and future business may be negatively affected because of the potential inability to obtain useful clinical data or increased costs and delays in completing the study.

We sponsor PROSPECT, a natural history study of plaque, with Abbott Vascular, a division of Abbott Laboratories. Pursuant to the terms of our collaboration agreement with Abbott Vascular, either party may terminate the agreement without cause upon 60 days notice. Abbott Vascular, or if sponsorship of the study is transferred by Abbott Vascular, a new collaborator may elect to delay or stop the PROSPECT study prematurely, causing a

disruption in gathering clinical data related to vulnerable plaque or limiting the number of patients enrolled. If we chose to continue the study without a collaborator, we would also have additional financial burdens. If we are unable to access the clinical data generated prior to termination, we may have to restart the study which would increase our financial burden and delay the timing of obtaining useful clinical data from the study. In the event that PROSPECT does not result in usable data and we are unable to prove a causal connection between vulnerable plaque and coronary events, the market for our vulnerable plaque products may not materialize. If we have to assume more of the financial burden of this clinical study, we would divert valuable financial and clinical resources from other areas of our business.

### Competition from companies that have longer operating histories and greater resources than us may harm our business.

The medical device industry, including the market for IVUS products, is highly competitive, subject to rapid technological change and significantly affected by new product introductions and market activities of other participants. As a result, even if the size of the markets in which we compete, including the IVUS market, increases, we can make no assurance that our revenues will increase. In addition, as the markets for medical devices, including IVUS products, develop, additional competitors could enter the market. To compete effectively, we will need to continue to demonstrate that our products are attractive alternatives to other devices and treatments. We believe that our continued success depends on our ability to:

- innovate and maintain scientifically advanced technology;
- · apply our technology across products and markets;
- · develop proprietary products;
- successfully conduct or sponsor clinical studies that expand our markets;
- obtain and maintain patent protection for our products;
- · obtain and maintain regulatory clearance or approvals;
- · cost-effectively manufacture and successfully market our products; and
- attract and retain skilled personnel.

With respect to our IVUS products, our largest competitor is Boston Scientific. We also compete in Japan with Terumo Corporation. Boston Scientific, Terumo and other potential competitors are substantially larger than us and may enjoy competitive advantages, including:

- more established distribution networks;
- entrenched relationships with physicians;
- products and procedures that are less expensive;
- broader range of products and services that may be sold in bundled arrangements;
- · greater experience in launching, marketing, distributing and selling products;
- greater experience in obtaining and maintaining the FDA and other regulatory clearances and approvals;
- · established relationships with healthcare providers and payors; and
- greater financial and other resources for product development, sales and marketing, acquisitions of products and companies, and intellectual property protection.

For these reasons, we may not be able to compete successfully against our current or potential future competitors, and sales of our products may decline.

Failure to innovate will adversely impact our competitive position and may adversely impact our product revenues.

Our future success will depend upon our ability to innovate new products and introduce enhancements to our existing products in order to address the changing needs of the marketplace. Frequently, product development programs require assessments to be made of future clinical need and commercial feasibility, which are difficult to predict. Customers may forego purchases of our products and purchase our competitors' products as a result of delays in introduction of our new products and enhancements, failure to choose correctly among technical alternatives or failure to offer innovative products or enhancements at competitive prices and in a timely manner. In addition, announcements of new products may result in a delay in or cancellation of purchasing decisions in anticipation of such new products. We may not have adequate resources to effectively compete in the marketplace. Any delays in product releases may negatively affect our business.

We also compete with new and existing alternative technologies that are being used to penetrate the worldwide vascular imaging market without using IVUS technology. These products, procedures or solutions could prove to be more effective, faster, safer or less costly than our IVUS products. Technologies such as angiography, angioscopy, multi-slice computed tomography, intravascular magnetic resonance imaging, or MRI, electron beam computed tomography, and MRI with contrast agents are being used to image the vascular system. The introduction of new products, procedures or clinical solutions by competitors may result in price reductions, reduced margins, loss of market share and may render our products obsolete. We cannot guarantee that these alternative technologies will not be commercialized and become viable alternatives to IVUS in the future, and we cannot guarantee that we will be able to compete successfully against them if they are commercialized.

# We manufacture our IVUS catheters, maintain our own customized equipment and are implementing a new manufacturing process, making us vulnerable to production and supply problems that could negatively impact our revenues.

We presently use customized equipment which is no longer produced or supported by a third party for the manufacture of the scanners located on our phased array catheters. This equipment was supported by the company that designed and manufactured it until 2002. That company ceased operations in 2002 because changes in manufacturing technology made the design and manufacture of similar equipment more mainstream and automated and made customized manufacturing equipment, such as ours, much less economical to build and support. Because of the customized nature of our equipment and the obsolescence of an industry to create or support such equipment, we cannot rely on third parties to find new parts or replace the equipment. As a result, we are responsible for maintaining the equipment and for locating spare parts. If the equipment malfunctions and we are unable to locate spare parts or hire qualified personnel to repair the equipment, we may encounter delays in the manufacture of our catheters and may not have sufficient inventory to meet our customers' demands, which could negatively impact our revenues.

We have engaged a third party to develop an automated system to replace this equipment. The automated system has been installed and is now manufacturing the scanners on the majority of our phased array catheters with all scanner production expected to be performed by this new system in the first quarter of 2008. The system is located at the third party's facility which requires us to be dependent on the third party for the day-to-day control and protection of the system as well as the sole sourcing of scanners once all scanner manufacturing is performed by the new system. We expect that in the event it is necessary to replace the third party for the assembly operation, it would take at least twelve months to identify and qualify an appropriate replacement supplier that is able to undertake the additional assembly operation.

In addition, it is likely that we will need to expand our manufacturing capacity within the next two years. We expect that any expansion would be achieved through modified space utilization in our current leased facilities, improved efficiencies, automation and acquisition of additional tooling and equipment. We may not have, or be able to obtain, the required funds to expand our manufacturing capacity if necessary.

### We are dependent on our collaborations, and events involving these collaborations or any future collaborations could delay or prevent us from developing or commercializing products.

The success of our current business strategy and our near- and long-term viability will depend on our ability to execute successfully on existing strategic collaborations and to establish new strategic collaborations. Collaborations allow us to leverage our resources and technologies and to access markets that are compatible with our own

core areas of expertise. To penetrate our target markets, we may need to enter into additional collaborative agreements to assist in the development and commercialization of future products. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position and our internal capabilities. Our discussions with potential collaborators may not lead to the establishment of new collaborations on favorable terms.

We have collaborations with Medtronic, Inc. and certain of its affiliates, or Medtronic, The Cleveland Clinic Foundation, GE, Philips and Siemens. In each collaboration, we combine our technology or core capabilities with that of the third party to either permit greater penetration into markets, as in the case of Medtronic, GE and Philips, or enhance the functionality of our current and planned products, as in the case of The Cleveland Clinic Foundation.

We have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborations or potential products. These collaborators may breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Further, our collaborators may not develop or commercialize products that arise out of our collaborative arrangements or devote sufficient resources to the development, manufacture, marketing or sale of these products. Moreover, in the event of termination of a collaboration agreement, termination negotiations may result in less favorable terms.

### Delays in planned product introductions may adversely affect our business and negatively impact future revenues.

We are currently developing new products and product enhancements with respect to our IVUS and FM products. We may experience delays in any phase of product development and commercial launch, including during research and development, manufacturing, limited release testing, marketing and customer education efforts. Any delays in our product launches may significantly impede our ability to successfully compete in the IVUS and FM markets and may reduce our revenues.

We launched the rotational catheter product for our IVUS IVG in the United States and Europe in the third quarter of 2006. We are developing a rotational catheter product for each of our s5 consoles. We launched the rotational catheter product for our IVUS IVG consoles in Japan in the second half of 2007 and plan to launch the rotational catheter product for our s5 consoles in the United States and Europe in the first half of 2008 and in Japan in the second half of 2008. We expect to launch our rotational catheter product for VH IVUS in the United States and Europe in the second half of 2008 and in Japan in the first half of 2009. To reach this goal, we must complete various stages of development, and it may be necessary to delay expected product launches to allow us to finalize product development. We have also been working to improve the design and functionality of our FM ComboMap product. Additional development steps, including manufacturing and product testing, will be necessary before these products can be launched. Any development delays resulting in a delayed launch may have a negative effect on our business, including lost or delayed revenue and decreased market acceptance.

Delays in our development of product enhancements or functionality may also adversely impact the sale of our IVUS consoles. We have entered into a software development and license agreement with Paieon to develop functionality that synchronizes IVUS and angiographic images to be included as part of our IVUS consoles. Although the initial development of IVUS and angiographic image co-registration functionality on our IVUS IVG consoles was completed in the second half of 2006, we have delayed further development of this functionality relative to our s5 consoles to solicit feedback from physicians regarding the use of the IVUS IVG consoles into which the co-registration functionality has been integrated. If we do not complete development, full functionality is not achieved or the product does not provide the anticipated benefit, we may not recoup the investment, and the sale of our IVUS consoles may be adversely impacted.

We and our present and future collaborators may fail to develop or effectively commercialize products covered by our present and future collaborations if:

- we do not achieve our objectives under our collaboration agreements;
- we or our collaborators are unable to obtain patent protection for the products or proprietary technologies we develop in our collaborations;

- we are unable to manage multiple simultaneous product discovery and development collaborations;
- · our collaborators become competitors of ours or enter into agreements with our competitors;
- · we or our collaborators encounter regulatory hurdles that prevent commercialization of our products; and
- we develop products and processes or enter into additional collaborations that conflict with the business
  objectives of our other collaborators.

In addition, conflicts may arise with our collaborators, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any conflicts arise with our existing or future collaborators, they may act in their self-interest, which may be adverse to our best interest.

If we or our collaborators are unable to develop or commercialize products, or if conflicts arise with our collaborators, we will be delayed or prevented from developing and commercializing products which will harm our business and financial results.

## If we choose to acquire new businesses, products or technologies, we may experience difficulty in the identification or integration of any such acquisition, and our business may suffer.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and technologies. Accordingly, we may in the future pursue the acquisition of complementary businesses, products or technologies instead of developing them ourselves. We do not know if we will be able to identify or complete any acquisitions, or whether we will be able to successfully integrate any acquired business, product or technology or retain key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we are unable to integrate any acquired businesses, products or technologies effectively, our business will suffer. In addition, any amortization or charges resulting from acquisitions could harm our operating results.

#### To market and sell our products, we depend on third-party distributors, and they may not be successful.

We currently depend on third-party distributors to sell our products. If these distributors are not successful in selling our products, we may be unable to increase or maintain our level of revenue. Over the long term, we intend to grow our business internationally, and to do so we will need to attract additional distributors to expand the territories in which we do not directly sell our products. Our distributors may not commit the necessary resources to market and sell our products. If current or future distributors do not perform adequately or if we are unable to locate distributors in particular geographic areas, we may not realize revenue growth internationally. In addition, in the event that we experience any difficulties under our March 2006 agreement with GE for our s5i and s5i GE Innova IVUS, or in coordinating our efforts with GE, our revenue from the sale of our s5i and s5i GE Innova IVUS products will be adversely affected.

A significant portion of our annual revenue is derived from sales to our Japanese distributors, primarily Goodman, Fukuda Denshi and Johnson & Johnson K.K., Medical Company (Johnson & Johnson). In the year ended December 31, 2007, we generated revenues of \$34.8 million from sales to our Japanese distributors. While these, in some cases, multi-level agreements allow us to access specific customers and markets, they create complex distribution arrangements and increase our reliance on our Japanese distributors. We entered into an agreement with Fukuda Denshi in March 2006 that extended our commercial relationship through June 2012. This agreement became effective upon the transfer of the related regulatory approvals held by Fukuda Denshi, which took place on June 1, 2006. During the second half of 2007, we also entered into distribution agreements with GE and Philips, and in January 2008, we entered into a distribution agreement with Siemens. A significant change in our relationship with our distributors or in the relationships between our distributors may have a negative impact on our ability to sustain and grow our business in Japan.

In certain other international markets, we also use distributors. Other than Japan, no one market in which we use distributors represents a significant portion of our revenues but, in the aggregate, problems with these distribution

arrangements could negatively affect our international sales strategy, negatively impact our revenues and the market price of our stock.

### The risks inherent in our international operations may adversely impact our revenues, results of operations and financial condition.

We derive, and anticipate we will continue to derive, a significant portion of our revenues from operations in Japan and Europe. In the year ended December 31, 2007, revenues to customers located in Japan and Europe were \$35.2 million and \$24.0 million, representing 26.9% and 18.4%, respectively, of our total revenue. As we expand internationally, we will need to hire, train and retain qualified personnel for our direct sales efforts and retain distributors and train their personnel in countries where language, cultural or regulatory impediments may exist. We cannot ensure that distributors, physicians, regulators or other government agencies will accept our products, services and business practices. In addition, we purchase some components on the international market. The sale and shipment of our products and services across international borders, as well as the purchase of components from international sources, subject us to extensive U.S. and foreign governmental trade regulations. Compliance with such regulations is costly. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities. Failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities. Our international sales operations expose us and our representatives, agents and distributors to risks inherent in operating in foreign jurisdictions, including:

- our ability to obtain, and the costs associated with obtaining, U.S. export licenses and other required export or import licenses or approvals;
- operating under government-run healthcare systems and changes in third-party reimbursement policies;
- changes in duties and tariffs, taxes, trade restrictions, license obligations and other non-tariff barriers to trade;
- · burdens of complying with a wide variety of foreign laws and regulations related to healthcare products;
- · costs of localizing product and service offerings for foreign markets;
- · business practices favoring local companies;
- longer payment cycles and difficulties collecting receivables through foreign legal systems;
- · difficulties in enforcing or defending agreements and intellectual property rights; and
- · changes in foreign political or economic conditions.

We cannot ensure that one or more of these factors will not harm our business. Any material decrease in our international revenues or inability to expand our international operations would adversely impact our revenues, results of operations and financial condition.

## We depend on one distributor to hold the regulatory approvals related to certain of our products imported into Japan and for ongoing regulatory compliance, and difficulties involving this relationship will impair our ability to sell these products in Japan.

Goodman currently distributes our FM and rotational IVUS products in Japan and is responsible for Japanese regulatory compliance in relation to these products, including obtaining and maintaining the applicable regulatory approvals and ensuring ongoing compliance with Japanese laws and regulations relating to importation and sale. We have neither the capability nor the authority to import or sell our FM and rotational IVUS products in Japan and are dependent on Goodman to do so. In the year ended December 31, 2007 and 2006, sales of our FM and rotational IVUS products in Japan accounted for 28.6% and 15.8%, respectively, of our FM and rotational IVUS product revenues and 4.2% and 1.9%, respectively, of our total revenues. Our distribution relationship with Goodman is based on an agreement executed in 1994. By its terms, this agreement expired in 1999 unless extended by mutual written agreement. No formal amendment to the agreement has extended its terms. However, Goodman and we have continued to operate in accordance with its terms, including the adoption of new pricing exhibits, placement and

fulfillment of orders, and payment of invoices, since we acquired certain FM assets in 2003. In July 2007, Goodman obtained regulatory approval relating to the importation and sale of our rotational catheter and certain related hardware in Japan. If Goodman fails to maintain regulatory compliance related to our FM and rotational products, we will be unable to sell these products in Japan. Furthermore, if Goodman successfully argues that it is under no obligation to distribute our products and ceases to distribute our products, we will no longer be able to sell these products in Japan.

Our manufacturing operations are dependent upon third party suppliers, which makes us vulnerable to supply problems, price fluctuations and manufacturing delays.

We rely on AMI Semiconductors, Inc., or AMIS, for the supply of application specific integrated circuits, or ASICs, and for the supply of wafers used in the manufacture of our IVUS IVG consoles and our catheters. These ASICs and wafers are critical to these products, and there are relatively few alternative sources of supply. We do not carry a significant inventory of either component. If we had to change suppliers, we expect that it would take at least a year, and possibly 18 months or longer, to identify an appropriate replacement supplier, complete design work and undertake the necessary inspections before the ASICs or wafers would be available. We rely on International Micro Industries, Inc., or IMI, to undertake additional processing of certain of the ASICs that are produced by AMIS for use in the manufacture of our catheters. We do not carry a significant inventory of the circuits that are finished by IMI. We expect that in the event it is necessary to replace IMI, it would take at least three months, and possibly six months or longer, to identify an appropriate replacement supplier that is able to undertake the additional processing on the ASICs. We are not parties to supply agreements with either AMIS or IMI but instead use purchase orders as needed.

Our former supplier of FM wire pressure sensors ceased production of this key component on 4" wafers. We secured an end-of-life purchase in 2007 of the subject parts equivalent to an estimated four-year supply. We believe this will provide us with adequate time to initiate and qualify a replacement supplier or new design to replace the product. We expect that it will take approximately 24 months to identify an appropriate replacement supplier, complete design work and undertake the necessary inspections before the new pressure sensors will be available.

We also rely upon Endicott Interconnect Technologies (EIT) for the assembly operation of the scanner used on the IVUS catheters. We do not carry a significant inventory of the scanner assemblies that are finished by EIT. We expect that in the event it is necessary to replace EIT for the assembly operation, it would take at least 12 months to identify and qualify an appropriate replacement supplier that is able to undertake the additional assembly operation. A Materials Supply Agreement is in place with EIT for the assembly of the scanner devices.

In addition, we implemented a new automated system to replace the customized equipment which is no longer produced or supported by a third party for the manufacture of the scanners located on our phased array catheters.

The new automated system is located at EIT's facility and we are dependent on EIT for the day-to-day control and protection of the system. If the new automated system does not perform as expected, or if we are not provided with the product as requested, or if we are not provided access to the system, we may encounter delays in the manufacture of our catheters and many not have sufficient inventory to meet our customers' demands, which could negatively impact our revenues.

Our reliance on these sole source suppliers subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including:

- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's variation in a component;
- uncorrected quality and reliability defects that impact performance, efficacy and safety of products from replacement suppliers;
- price fluctuations due to a lack of long-term supply arrangements for key components with our suppliers;

- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- · delays in delivery by our suppliers due to changes in demand from us or their other customers.

Any significant delay or interruption in the supply of components or materials, or our inability to obtain substitute components or materials from alternate sources at acceptable prices and in a timely manner, could impair our ability to meet the demand of our customers and harm our business. Identifying and qualifying additional or replacement suppliers for any of the components or materials used in our products may not be accomplished quickly or at all and could involve significant additional costs. Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components or materials used to manufacture our products would limit our ability to manufacture our products and could therefore have a material adverse effect on our business, financial condition and results of operations.

In addition, it is likely that we will need to expand our manufacturing capacity within the next two years. We expect that any expansion would be achieved through modified space utilization in our current leased facilities, improved efficiencies, automation and acquisition of additional tooling and equipment. We may not have, or be able to obtain, the required funds to expand our manufacturing capacity if necessary.

### We may require significant additional capital to pursue our growth strategy, and our failure to raise capital when needed could prevent us from executing our growth strategy.

We believe that our existing cash and cash equivalents and short-term available-for-sale investments will be sufficient to meet our anticipated cash needs for at least the next 12 months. However, we may need to obtain additional financing to pursue our business strategy, to respond to new competitive pressures or to act on opportunities to acquire or invest in complementary businesses, products or technologies. The timing and amount of our working capital and capital expenditure requirements may vary significantly depending on numerous factors, including:

- market acceptance of our products;
- the revenues generated by our products
- the need to adapt to changing technologies and technical requirements, and the costs related thereto;
- the costs associated with expanding our manufacturing, marketing, sales and distribution efforts; and
- the existence and timing of opportunities for expansion, including acquisitions and strategic transactions.

If our capital resources are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or to obtain debt financing. The sale of additional equity or debt securities, or the use of our stock in an acquisition or strategic transaction, would result in additional dilution to our stockholders. Additional debt would result in increased expenses and could result in covenants that would restrict our operations. Our significant losses to date may prevent us from obtaining additional funds on favorable terms, if at all. We have not made arrangements to obtain additional financing, and there is no assurance that financing, if required, will be available in amounts or on terms acceptable to us, if at all.

### If we are unable to recruit, hire and retain skilled and experienced personnel, our ability to effectively manage and expand our business will be harmed.

Our success largely depends on the skills, experience and efforts of our officers and other key employees who may terminate their employment at any time. The loss of any of our senior management team, in particular our President and Chief Executive Officer, R. Scott Huennekens, could harm our business. We have entered into employment contracts with R. Scott Huennekens and our Chief Financial Officer, John T. Dahldorf, but these agreements do not guarantee that they will remain employed by us in the future. The announcement of the loss of one of our key employees could negatively affect our stock price. Our ability to retain our skilled workforce and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. We face challenges in hiring, training, managing and retaining employees in certain areas including

clinical, technical, sales and marketing. This could delay new product development and commercialization, and hinder our marketing and sales efforts, which would adversely impact our competitiveness and financial results.

#### If we fail to properly manage our anticipated growth, our business could suffer.

Rapid growth of our business is likely to place a significant strain on our managerial, operational and financial resources and systems. To execute our anticipated growth successfully, we must attract and retain qualified personnel and manage and train them effectively. In addition, we anticipate hiring additional personnel to assist in the commercialization of our current products and in the development of future products. We will be dependent on our personnel and third parties to effectively market and sell our products to an increasing number of customers. We will also depend on our personnel to develop and manufacture new products and product enhancements. Further, our anticipated growth will place additional strain on our suppliers resulting in increased need for us to carefully monitor for quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

### Future interest income and the value of our investments may be impacted by further declines in interest rates and the broader effect of the recent disruption of credit markets.

We are conservative in our investment policies and invest our excess cash primarily in corporate notes, money market funds and U.S. municipal debt securities. As of December 31, 2007, we have invested in money market funds and securities issued by banks and corporations. The interest paid on these types of investments and the value of certain securities may decline in the future as credit markets adjust to the mortgage crisis. While our investment portfolio has not yet been adversely impacted, if there is continued and expanded disruption in the credit markets, our investment portfolio could be adversely affected in the future.

### Fluctuations in foreign currency exchange rates could result in declines in our reported revenues and earnings.

Our reported revenues and earnings are subject to fluctuations in currency exchange rates. We do not engage in foreign currency hedging arrangements, and, consequently, foreign currency fluctuations may adversely affect our revenues and earnings.

### Our FM products have one competitor who, if more successful at commercializing its product, may cause us to lose market share which would adversely impact our business.

Our FM products compete with the products of Radi Medical Systems AB, a privately-held company based in Sweden. As Radi is a privately-held company without any public reporting obligations, the actual size of the FM market is difficult to ascertain. If we are unable to effectively demonstrate that our products offer greater applicability and enhanced functionality or other benefits compared to products of Radi or future competitors, we could fail to expand or penetrate the existing FM market. Since certain of our current and anticipated products are specifically developed for the FM market, our failure to achieve greater market penetration and market expansion would harm our financial condition and results of operations.

### If we become profitable, we cannot assure you that our net operating losses will be available to reduce our tax liability.

Our ability to use our net operating losses to reduce future income tax obligations may be limited or reduced. Generally, a change of more than 50 percentage points in the ownership of our shares, by value, over the three-year period ending on the date the shares were acquired constitutes an ownership change and may limit our ability to use net operating loss carryforwards. Furthermore, the number of shares of our common stock issued in our initial public offering and our follow-on offerings may be sufficient, taking into account prior or future changes in our ownership over a three-year period, to cause us to undergo an ownership change. As a result, our ability to use our existing net operating losses to offset U.S. taxable income may also become subject to substantial limitations. Further, the amount of our net operating losses could be reduced if any tax deductions taken by us are limited or disallowed by the Internal Revenue Service. All of these limitations could potentially result in increased future tax liability for us.

The expense and potential unavailability of insurance coverage for our company, customers or products may have an adverse effect on our financial position and results of operations.

While we currently have insurance for our business, property, directors and officers, and products, insurance is increasingly costly and the scope of coverage is narrower, and we may be required to assume more risk in the future. If we are subject to claims or suffer a loss or damage in excess of our insurance coverage, we will be required to cover the amounts in excess of our insurance limits. If we are subject to claims or suffer a loss or damage that is outside of our insurance coverage, we may incur significant costs associated with loss or damage that could have an adverse effect on our financial position and results of operations. Furthermore, any claims made on our insurance policies may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all. We do not have the financial resources to self-insure, and it is unlikely that we will have these financial resources in the foreseeable future.

We have product liability insurance that covers our products and business operation, but we may need to increase and expand this coverage commensurate with our expanding business. Any product liability claims brought against us, with or without merit, could result in:

- · substantial costs of related litigation or regulatory action;
- · substantial monetary penalties or awards;
- · decreased demand for our products;
- reduced revenue or market penetration;
- · injury to our reputation;
- · withdrawal of clinical study participants;
- · an inability to establish new strategic relationships;
- increased product liability insurance rates; and
- · prevention of securing continuing coverage.

Some of our customers and prospective customers may have difficulty in procuring or maintaining liability insurance to cover their operation and use of our products. Medical malpractice carriers are withdrawing coverage in certain regions or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and potential customers may opt against purchasing our products due to the cost or inability to procure insurance coverage.

#### Risks Related to Government Regulation

If we fail to obtain, or experience significant delays in obtaining, regulatory clearances or approvals for our products or product enhancements, our ability to commercially distribute and market our products could suffer.

Our products are subject to rigorous regulation by the FDA and numerous other Federal, state and foreign governmental authorities. Our failure to comply with such regulations could lead to the imposition of injunctions, suspensions or loss of regulatory clearances or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities are possible. The process of obtaining regulatory authorizations to market a medical device, particularly from the FDA, can be costly and time consuming, and there can be no assurance that such authorizations will be granted on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received 510(k) clearance or is the subject of an approved pre-market approval, or PMA, application. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The PMA approval process is more costly, lengthy and uncertain than the 510(k) clearance process. Introduction to the market of products we develop that require regulatory clearance or approval may be delayed. In addition, because we cannot assure you that any new products

or any product enhancements we develop will be subject to the shorter 510(k) clearance process, the regulatory approval process for our products or product enhancements may take significantly longer than anticipated. There is no assurance that the FDA will not require that a new product or product enhancement go through the lengthy and expensive PMA approval process. To date, all of our products have been cleared through the 510(k) process. We have no experience in obtaining PMA approvals.

In the 27 member states of the European Union, or E.U., there is a consolidated system for the authorization of medical devices. The system of regulating medical devices operates by way of a certification for each medical device. Each certificated device is marked with a CE mark which shows that the device has a Certificat de Conformité. There are national bodies, known as Competent Authorities, in each member state that oversee the implementation of the E.U. Medical Device Directive within their jurisdiction.

The means for achieving the requirements for a CE mark vary according to the nature of the device. Under the requirements of E.U. member states, our products are required to be assessed by a Notified Body. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states. Our products, including their design and manufacture, have been certified by the British Standards Institute, or BSI, in the United Kingdom as being compliant with the requirements of E.U. law. Consequently, we are entitled to affix a CE mark to our products and their packaging and this gives us the right to sell them in Europe.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent, and to the extent we continue to market and sell our products in foreign countries, we will be subject to rigorous regulation in the future. In such circumstances, we would rely significantly on our distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

We have conducted, but are not currently conducting, clinical studies with some of our products under an investigational device exemption. Clinical studies must be conducted in compliance with regulations of the FDA and those of regulatory agencies in other countries in which we conduct clinical studies. The data collected from these clinical studies will ultimately be used to support market clearance for these products. There is no assurance that U.S. or foreign regulatory bodies will accept the data from these clinical studies or that they will ultimately allow market clearance or approval for these products. Regulatory delays or failures to obtain clearances and approvals could disrupt our business, harm our reputation and adversely affect our sales.

### Modifications to our products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until clearances are obtained.

Modifications to our products may require new 510(k) clearances or PMA approvals or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a PMA approval. Where we determine that modifications to our products require a new 510(k) clearance or PMA approval, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. For those products sold in the European Union, we must notify BSI, our E.U. Notified Body, if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Delays in obtaining required future

clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

### If we fail to adequately manage our regulatory responsibilities following the Japanese regulatory approvals, our ability to sell our IVUS products in Japan would be impaired.

We currently market our IVUS products in Japan under two types of regulatory approval known as a SHONIN and a NINSHO. SHONINS for medical devices are issued by Japan's Ministry of Health, Labour and Welfare to a Marketing Authorization Holder, or MAH, who thereafter holds the SHONINS for, or possesses regulatory approval permitting the import of such devices into Japan. NINSHOS for medical devices are issued by MHLW-approved third-party agencies such as BSI-Japan. Under the third-party program, only certain devices are authorized to be reviewed and approved in this manner. Our IVUS imaging consoles fall within this category and we have elected to participate in this program and have received approval for the s5i. The SHONINS for our IVUS products were previously held by Fukuda Denshi, the MAH for our IVUS products, who acted as our importer and one of our Japanese distributors and has been responsible for our regulatory compliance in Japan. Until June 1, 2006, we did not have the authority to import or sell our IVUS products directly in Japan, and we were dependent on Fukuda Denshi to do so.

Fukuda Denshi transferred the SHONINs for our IVUS products to us on June 1, 2006. Due to the transfer of the SHONINs, responsibility for Japanese regulatory filings and future compliance resides with us. There is a risk that the transfer of the SHONINs and regulatory responsibility will lead to disruption or lack of coordination in our ongoing compliance activities in Japan. As the holder of the SHONINs, we have the authority to import and sell those IVUS products for which we have the SHONINs as well as those products which we have obtained a NINSHO; but are subject to greater scrutiny. As such, we have to dedicate greater internal resources to direct regulatory compliance in Japan. We cannot guarantee that we will be able to adequately meet the increased regulatory responsibilities. Non-compliance with Japanese regulations may result in action to prohibit further importation and sale of our products in Japan, a significant market for our products. Goodman K.K. holds the SHONIN for our rotational product line; the Revolution catheter and the IVG with SpinVision. In these two product cases, Goodman is the MAH who imports these devices and all of the regulatory responsibility of an MAH for these two devices is the responsibility of Goodman.

As a holder of SHONINs and NINSHOs, we are required to import those products for which we are MAH directly through our Japanese subsidiary and sell to our distributors from our subsidiary. At present, we do not have the capabilities to support direct importation and sales of products to our distributors. As a result, we have retained a third party to provide this support. We have limited operating history with this third party and cannot guarantee that it or any other party will adequately support importation and sales of products to our distributors. If we cannot establish the infrastructure to import our products or if support is not adequately provided by a third party, our ability to import and sell our products in Japan would be impaired. If we are unable to sell our IVUS products in Japan, we will lose a significant part of our annual revenues, and our business will be substantially impacted.

### Changes in the Japanese regulatory requirements for medical devices could impact our ability to market our products in Japan and subject us to fines, penalties or other sanctions.

In April 2005, Japan changed the law regarding medical device approvals to require that SHONINs include additional information beyond what had been required in the past, including information about manufacturing processes, shipping and other raw materials used. Companies are not required by the revised law to withdraw their existing SHONINs, and the revised law states that SHONINs approved under the prior law will still be considered valid. However, importers marketing products in Japan must update their SHONINs on a five-year cycle, and the updates are expected to include the additional information required by the revised law.

These new regulations increase the regulatory and quality assurance requirements for both our manufacturing facilities and our efforts in obtaining and maintaining regulatory approvals in Japan. While parts of the new regulations are still being defined, we expect that the new regulations may result in higher costs and delays in securing approval to market our products in Japan.

We expect to file new SHONIN applications for our IVUS catheters and our IVUS IVG consoles sometime between 2008 and 2010, although we are not required under the Japanese regulatory laws to do so until 2010 and we may

decide to file such new SHONIN applications at a time that is deemed advantageous. This new filing will comply with the new law which encompasses design, manufacturing, shipping and quality processes. In connection with the new law, the Japanese government has prepared new guidance documents, including one document that addresses raw materials, that, along with the new law, greatly expand the required content of the product approval application from the prior law. With the existing SHONINs, we relied on Fukuda Denshi's regulatory expertise that the product approval applications appropriately reflected our devices and therefore were in compliance with the law at the time as well as its assessment regarding continuing compliance with the law over the years. We are now the MAH for our IVUS products and have full responsibility for their continued legal compliance in Japan.

We cannot guarantee that the Japanese regulatory authorities will not take a different view of compliance with the existing SHONINs and conclude that because the new laws require inclusion of new information, we must cease marketing or even recall our IVUS catheters until we have updated, and received approval of, our SHONIN to include the additional information required by the new law. Alternatively, the Japanese regulatory authorities could disagree with our distributor's past conclusions and determine that we should have disclosed this information in the earlier SHONINs that were filed under prior law, and they could require us to cease marketing, recall the product or impose other regulatory penalties. In the event that the Japanese regulatory authorities come to such a conclusion and take corrective action, our business will suffer from lost revenue, lost reputation and lost market share.

### If we or our suppliers fail to comply with the FDA's Quality System Regulation or ISO Quality Management Systems, manufacturing of our products could be negatively impacted and sales of our products could suffer.

Our manufacturing processes and those of our suppliers are required to comply with the FDA's Quality System Regulation, or QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. We are also subject to similar state and foreign requirements and licenses, known as ISO Quality Management Systems, or QMS. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facilities and records for periodic inspections by governmental agencies, including the FDA, state authorities and comparable foreign agencies. If we fail to comply with the QSR or QMS, our operations could be disrupted and our manufacturing interrupted.

Failure to take adequate corrective action in response to an adverse Quality System inspection could result in, among other things, a shut-down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our devices, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

We were inspected by the FDA in 2004 and in 2006. The 2004 inspection resulted in two inspectional observations on FDA Form 483. The 2006 inspection resulted in three inspectional observations on FDA Form 483. We have responded to these observations and believe that we have adequately completed all necessary evaluation of, and implementation of adjustments to, the affected processes. The FDA has acknowledged our response to the audit and has indicated that the corrective actions should adequately address the inspectional observations.

Inspections by the E.U. Notified Body are conducted biannually or annually and the E.U. Notified Body also has the right to make unannounced visits to our manufacturing facility. We were inspected by the E.U. Notified Body in December 2005, February 2007, June 2007, and October 2007. No major nonconformities were reported in the December 2005, February 2007, and October 2007 inspections. In the inspection in June 2007, one major nonconformity was identified. A corrective action plan was submitted and accepted by the Notified Body. As a result, continued ISO 13485:2003 certification was granted. The certification is subject to biannual assessments until April 2008 to reassess the corrective actions. Failure to meet the corrective action plan may result in a suspension of the ISO 13485:2003 certification, which may affect revenues associated with all non-US markets.

We believe that we have taken sufficient corrective actions to address the observations and non-conformities noted by the FDA and the E.U. Notified Body, but there can be no assurance that our actions will satisfy the FDA and the E.U. Notified Body may impose additional inspections or audits at any time

and may conclude that our quality system is improperly validated or not otherwise in compliance with applicable regulations. Such findings potentially could disrupt our business, harm our reputation and adversely affect our sales.

### Our products may in the future be subject to product recalls or voluntary market withdrawals that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture that could affect patient safety. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated recall or voluntary recall or market withdrawal by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. For example, we are currently conducting a field correction, designated by FDA as a Class III recall, to replace monitors on certain s5i equipment, which were responsible for emissions slightly exceeding electromagnetic compatibility for the product. Recalls or voluntary withdrawals of any of our products would divert managerial and financial resources, and have an adverse effect on our financial condition and results of operations. A recall or voluntary withdrawal could harm our reputation with customers, affect revenues and negatively affect our stock price.

## If our products, or malfunction of our products, cause or contribute to death or serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has or may have a malfunction that would likely cause or contribute to death or serious injury if the malfunction were to recur. All manufacturers placing medical devices on the market in the European Union are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the Competent Authority in whose jurisdiction the incident occurred. Were this to happen to us, the relevant Competent Authority would file an initial report, and there would then be a further inspection or assessment if there are particular issues. This would be carried out either by the Competent Authority or it could require that the BSI, as the Notified Body, carry out the inspection or assessment.

Malfunction of our products, such as the separation of catheter tips during procedures, could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Such malfunctions have been reported to us on 24 occasions since July 2003. No injury to patients resulted from any of these incidents, but we can make no assurance that any future incident would not result in harm to patients. Upon learning of the malfunctions, we have taken all actions required by law and notified the appropriate regulatory authorities, including the FDA. We investigated each of the incidents, and found no evidence that the catheters were manufactured incorrectly. Product mishandling may contribute to or cause a separation or other product malfunction. Our product labeling includes a warning statement to avoid pulling the catheter if resistance is felt, but we can make no assurance that our products will be handled properly. While we do not believe there was any deficiency in any product, we cannot guarantee that malfunctions will not occur in the future. If they do occur, we may elect to take voluntary corrective action, and we may be subject to involuntary corrective action such as notification, fines, seizures or recalls. If someone is harmed by a malfunction or by product mishandling, we may be subject to product liability claims. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

### Failure to obtain regulatory approval in additional foreign jurisdictions will prevent us from expanding the commercialization of our products abroad.

We intend to market our products in a number of international markets. Although certain of our IVUS products have been approved for commercialization in Japan and in the European Union, in order to market our products in other

foreign jurisdictions, we have had to, and will need to in the future, obtain separate regulatory approvals. The approval procedure varies among jurisdictions and can involve substantial additional testing. Approval by the FDA does not ensure approval by regulatory authorities in other jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign jurisdictions or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval in addition to other risks. In addition, the time required to obtain foreign approval may differ from that required to obtain FDA approval, and we may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any foreign market other than in the European Union and Japan.

We may be subject to Federal, state and foreign healthcare fraud and abuse laws and regulations and other regulatory reforms, and a finding of failure to comply with such laws, regulations and reforms could have a material adverse effect on our business.

Our operations may be directly or indirectly affected by various broad Federal and state healthcare fraud and abuse laws. These include the Federal anti-kickback statute, which prohibits any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in return for or to induce the referring, ordering, leasing, purchasing or arranging for or recommending the ordering, purchasing or leasing of an item or service, for which payment may be made under Federal healthcare programs, such as the Medicare and Medicaid programs. The Federal anti-kickback statute, a felony statute, is very broad in scope, and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, many states have adopted laws similar to the Federal anti-kickback statute, and some of these laws are broader than that statute in that their prohibitions are not limited to items or services paid for by a Federal healthcare program but, instead, apply regardless of the source of payment.

Our financial relationships with healthcare providers and others who provide products or services to Federal healthcare program beneficiaries or are in a position directly or indirectly to recommend or arrange for use of our products are potentially governed by the Federal anti-kickback statute and similar state laws. If our past or present operations, including our consulting arrangements with physicians who use our products, are found to be in violation of these laws, we or our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from Medicare and Medicaid program participation. In connection with their services, some physicians serve as consultants and have in the past been awarded options to purchase our common stock. As of December 31, 2007, 90,906 shares of common stock have been purchased in connection with the exercise of these options and options to purchase 27,272 shares of common stock remain outstanding, vested and exercisable. Additionally, some are paid consulting fees or reimbursed for expenses. If enforcement action were to occur, our business and financial condition would be harmed.

In addition, Federal and state authorities and private whistleblower plaintiffs recently have brought actions against manufacturers alleging that the manufacturers' activities constituted aiding and abetting healthcare providers in the submission of false claims, or alleging that the manufacturers themselves made false or misleading statements to the Federal government. Such investigations or litigation could be time-consuming and costly to us and could divert management's attention from operating our business, which could have a material adverse effect on our business. In addition, if our activities were found to violate Federal or state false claims provisions, it could have a material adverse effect on our business and results of operations.

We do not believe that we are now subject to state or federal physician self-referral laws, but changes in federal or state legislation or regulatory interpretations could occur. Federal physician self-referral legislation (commonly known as the "Stark Law") prohibits, subject to certain exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain "designated health services" if the physician or an immediate family member has any financial relationship with the entity. The Stark Law also prohibits the entity receiving the referral from billing any good or service furnished pursuant to an unlawful referral, and any person collecting any amounts in connection with an unlawful referral is obligated to refund such amounts. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to \$100,000 for each such arrangement or scheme. The penalties for violating the Stark Law also include civil monetary penalties of up to \$15,000 per referral and possible exclusion from federal healthcare programs such as Medicare and Medicaid. Various states have corollary

laws to the Stark Law, including laws that require physicians to disclose any financial interest they may have with a healthcare provider to their patients when referring patients to that provider. Both the scope and exceptions for such laws vary from state to state.

We could also be subject to investigation and enforcement activity under Title II of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created two new federal crimes. A healthcare fraud statute that prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. A violation of these statutes is a felony and could result in fines, imprisonment or exclusion from government-sponsored programs. Additionally, HIPAA granted expanded enforcement authority to the Department of Health and Human Services and the U.S. Department of Justice and provided enhanced resources to support investigative and enforcement activities by governmental entities regarding fraud and abuse violations relating to healthcare delivery and payment.

In the United States, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. Federal and state lawmakers regularly propose and, at times, enact new legislation establishing significant changes in the healthcare system. We cannot predict whether new Federal legislation will be enacted in the future or the full impact that any such new legislation will have on our business. The potential for adoption of healthcare reform proposals on a state-by-state basis could require us to develop state-specific marketing and sales approaches. In addition, we may experience pricing pressures in connection with the sale of our products due to additional legislative proposals or healthcare reform initiatives. Our results of operations and our business could be adversely affected by future healthcare reforms. In the European Union, legislation on inducements offered to physicians and other healthcare workers or hospitals differ from country to country. Breach of the laws relating to such inducements may expose us to the imposition of criminal sanctions. It may also harm our reputation, which could in turn affect sales.

# If our customers are unable to obtain coverage of or sufficient reimbursement for procedures performed with our products, it is unlikely that our products will be widely used.

Successful sales of our products will depend on the availability of adequate coverage and reimbursement from third-party payors. Healthcare providers that purchase medical devices for treatment of their patients generally rely on third-party payors to reimburse all or part of the costs and fees associated with the procedures performed with these devices. Both public and private insurance coverage and reimbursement plans are central to new product acceptance. Customers are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products and related procedures.

To the extent we sell our products internationally, market acceptance may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Coverage, reimbursement, and healthcare payment systems in international markets vary significantly by country, and by region in some countries, and include both government-sponsored healthcare and private insurance. We may not obtain international reimbursement approvals in a timely manner, if at all. Our failure to receive international coverage or reimbursement approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

To date, our products have generally been covered as part of procedures for which reimbursement has been available. However, in the United States, as well as in foreign countries, government-funded or private insurance programs, commonly known as third-party payors, pay the cost of a significant portion of a patient's medical expenses. No uniform policy of coverage or reimbursement for medical technology exists among all these payors. Therefore, coverage of and reimbursement for medical technology can differ significantly from payor to payor.

All third-party coverage and reimbursement programs, whether government funded or insured commercially, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling healthcare costs through limitations on covered items and services, prospective reimbursement and capitation programs, group purchasing, redesign of benefits, second opinions required prior to major surgery, careful review of bills, encouragement of healthier lifestyles and exploration of more cost-effective methods of delivering healthcare.

These types of programs and legislative changes to coverage and reimbursement policies could potentially limit the amount which healthcare providers may be willing to pay for medical devices.

We believe that future coverage and reimbursement may be subject to increased restrictions both in the United States and in international markets. Third-party reimbursement and coverage for our products may not be available or adequate in either the United States or international markets. Future legislation, regulation, coverage or reimbursement policies of third-party payors may adversely affect the growth of the IVUS and FM markets, the demand for our existing products or our products currently under development, and limit our ability to sell our products on a profitable basis.

## Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject us to significant liability.

We use hazardous materials in our research and development and manufacturing processes. We are subject to Federal, state and local regulations governing use, storage, handling and disposal of these materials and associated waste products. We are currently licensed to handle such materials, but there can be no assurance that we will be able to retain those licenses in the future or obtain licenses under new regulations if and when they are required by governing authorities. Although we believe our procedures for use, storage, handling and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources and any applicable insurance. We have also incurred and may continue to incur expenses related to compliance with environmental laws. Such future expenses or liability could have a significant negative impact on our business, financial condition and results of operations. Further, we cannot assure that the cost of compliance with these laws and regulations will not materially increase in the future.

## The use, misuse or off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.

Our currently marketed products have been cleared by the FDA for particular indications for the qualitative and quantitative evaluation of the coronary and peripheral vasculature. Our products are also CE marked, licensed in Canada, have approvals in Japan, as well as regulatory approvals in many other countries around the world for specific indications for use. There may be increased risk of injury if physicians attempt to use our products in procedures outside of those indications cleared for use, known as off-label use. Our sales force does not promote our products for off-label uses, and our instructions for use in all markets specify that our products are not intended for use outside of those indications cleared for use. However, we cannot prevent a physician from using our products for off-label applications. Our catheters and guide wires are intended to be single-procedure products. In spite of clear labeling and instructions against reuse, we are aware that certain physicians have elected to reuse our products. Reuse of our catheters and guide wires may increase the risk of product liability claims. Reuse may also subject the party reusing the product to regulatory authority inspection and enforcement action. Physicians may also misuse our product if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us.

#### Risks Related to Our Intellectual Property and Potential Litigation

### Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.

Our success depends significantly on our ability to protect our intellectual property and proprietary technologies. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our pending U.S. and foreign patent applications may not issue as patents or may

not issue in a form that will be advantageous to us. Among other reasons, for example, the U.S. Patent and Trademark Office has recently promulgated new rules under 37 CFR Part I, that may affect the number of patents, the number of claims, or the scope of protection we may eventually obtain. Any patents we have obtained or do obtain may be challenged by re-examination, opposition or other administrative proceeding, or may be challenged in litigation, and such challenges could result in a determination that the patent is invalid. In addition, competitors may be able to design alternative methods or devices that avoid infringement of our patents. To the extent our intellectual property protection offers inadequate protection, or is found to be invalid, we are exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

In addition to pursuing patents on our technology, we have taken steps to protect our intellectual property and proprietary technology by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate.

In the event a competitor infringes upon our patent or other intellectual property rights, litigation to enforce our intellectual property rights or to defend our patents against challenge, even if successful, could be expensive and time consuming and could require significant time and attention from our management. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against challenges from others.

The medical device industry is characterized by patent litigation, and we could become subject to litigation that could be costly, result in the diversion of our management's time and efforts, require us to pay damages or prevent us from selling our products.

The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether or not a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Our competitors may assert that they own U.S. or foreign patents containing claims that cover our products, their components or the methods we employ in the manufacture or use of our products. In addition, we may become a party to an interference proceeding declared by the U.S. Patent and Trademark Office to determine the priority of invention. Because patent applications can take many years to issue and in many instances at least 18 months to publish, there may be applications now pending of which we are unaware, which may later result in issued patents that contain claims that cover our products. There could also be existing patents, of which we are unaware, that contain claims that cover one or more components of our products. As the number of participants in our industry increases, the possibility of patent infringement claims against us also increases.

Any interference proceeding, litigation or other assertion of claims against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of our management from our core business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to be infringing, we could be required to pay substantial damages and/or royalties and could be prevented from selling our products unless we could obtain a license or were able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may be unable to make, use, sell or otherwise commercialize one or more of our products. In addition, if we are found to willfully infringe, we could be required to pay treble damages, among other penalties.

We expect to enter new product fields, such as the IVUS guided therapies and ICE field, in the future. Entering such additional fields may subject us to claims of infringement. Defending any infringement claims would be expensive and time consuming.

We are aware of certain third-party U.S. patents related to pressure sensor guide wires and instrumentation. We do not have licenses to these patents nor do we believe that such licenses are required to develop, commercialize or sell our pressure sensor guide wires. However, the owners of these patents may initiate a lawsuit alleging infringement of one or more of these patents. If they do, we may be required to incur substantial costs related to patent litigation, which could place a significant strain on our financial resources and divert the attention of management from our business and harm our reputation. Adverse determinations in such litigation could cause us to redesign or prevent us from manufacturing or selling our pressure sensor guide wires and instrumentation, which would have an adverse effect on our business by limiting our ability to generate revenues through the sale of our FM guide wires.

From time to time in the ordinary course of business, we receive letters from third parties advising us of third-party patents that may relate to our business. The letters do not explicitly seek any particular action or relief from us. Although these letters do not threaten legal action, these letters may be deemed to put us on notice that continued operation of our business might infringe intellectual property rights of third parties. We do not believe we are infringing any such third-party rights, and we are unaware of any litigation or other proceedings having been commenced against us asserting such infringement. We cannot assure you that such litigation or other proceedings may not be commenced against us in the future.

# Our rights to a worldwide license of certain IVUS patents owned or licensed by Boston Scientific may be challenged.

The marketing and sale of our rotational IVUS catheters and pullback products depend on a license to IVUS-related patents owned or licensed by Boston Scientific. Boston Scientific was required to transfer the related intellectual property rights pursuant to a 1995 order of the Federal Trade Commission. We obtained rights to the license in 2003 through our former wholly-owned subsidiary, Pacific Rim Medical Ventures, which merged into us on December 30, 2004. In the event Boston Scientific disputes our rights to the license or seeks to terminate the license, we may be required to expend significant time and resources defending our rights. An adverse determination could cause us to redesign or prevent us from manufacturing or selling our rotational IVUS catheters and pullback products, which would have an adverse effect on our business. Additionally, in the event that the chain of title from the 1995 transfer of rights from Boston Scientific through the 2003 transfer to us is challenged, we may have fewer rights to the technology than our business requires which will negatively impact our ability to continue our development of rotational IVUS catheters and pullback products or subject us to disputes with Boston Scientific or others with respect to the incorporation of intellectual property into our products.

# Our VH IVUS business depends on a license from The Cleveland Clinic Foundation, the loss of which would severely impact our business.

The marketing and sale of our VH IVUS functionality for IVUS depends on an exclusive license to patents owned by The Cleveland Clinic Foundation, the license to which we obtained in April 2002. We are aware that maintenance of the license depends upon certain provisions being met by us including payment of royalties, commercialization of the licensed technology and obtaining regulatory clearances or approvals. If The Cleveland Clinic Foundation were to claim that we committed material breach or default of these provisions and we were not able to cure such breach or default, The Cleveland Clinic Foundation would have a right to terminate the agreement. The loss of the rights granted under the agreement could require us to redesign our VH IVUS functionality or prevent us from manufacturing or selling our IVUS products containing VH IVUS in countries covered by these patents. In addition, our exclusive license shall become non-exclusive if we fail to obtain regulatory clearances or approvals to commercialize the licensed technology within a proscribed time period. The cost of redesigning or inability to sell our VH IVUS products will have a negative impact on our ability to grow our business and may cause a drop in our stock price.

#### Risks Related to Our Common Stock

#### We expect that the price of our common stock will fluctuate substantially.

The market price of our common stock could be subject to significant fluctuation. Factors that could cause volatility in the market price of our common stock include the following:

- changes in earnings estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' earning estimates;
- · quarterly variations in our or our competitors' results of operations
- changes in governmental regulations or in the status of our regulatory clearance or approvals;
- · changes in availability of third-party reimbursement in the United States or other countries;
- the announcement of new products or product enhancements by us or our competitors;
- the announcement of an acquisition or other business combination or strategic transaction;
- · announcements related to patents issued to us or our competitors and to litigation;
- · sales of large blocks of our common stock, including sales by our executive officers and directors; and
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

These factors may materially and adversely affect the market price of our common stock.

# Future equity issuances or a sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

On December 31, 2007, the holders of up to 17,776,680 shares of our common stock may require us, subject to certain conditions, to file a registration statement covering those shares. If any of these stockholders cause a large number of securities to be sold in the public market, the sales could reduce our stock price. In addition, sales of these shares could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. Because we may need to raise additional capital in the future to continue to expand our business and develop new products, among other things, we may conduct additional equity offerings. These future equity issuances, together with any additional shares issued in connection with acquisitions, will result in further dilution to investors. As of December 31, 2007, options to purchase 5,337,000 shares of our common, stock were outstanding under our equity compensation plans. No prediction can be made regarding the effect that future sales of shares of our common stock will have on the market price of shares.

# Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of December 31, 2007, our directors, officers and principal stockholders each holding more than 5% of our common stock collectively controlled 40.2% of our outstanding common stock. To the extent our directors, officers and principal stockholders continue to hold a significant percentage of our outstanding common stock, these stockholders, if they act together, would be able to exert significant influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

# Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws and Delaware law could discourage a takeover.

Our amended and restated certificate of incorporation and bylaws and Delaware law contain provisions that might enable our management to resist a takeover. These provisions include:

a classified board of directors;

- advance notice requirements to stockholders for matters to be brought at stockholder meetings;
- a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws; and
- the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer.

We are also subject to the provisions of Section 203 of the Delaware General Corporation Law that, in general, prohibit any business combination or merger with a beneficial owner of 15% or more of our common stock unless the holder's acquisition of our stock was approved in advance by our board of directors. These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

We have adopted a stockholder rights plan that may discourage, delay or prevent a change of control and make any future unsolicited acquisition attempt more difficult. Under the rights plan:

- the rights will become exercisable only upon the occurrence of certain events specified in the plan, including the acquisition of 20% of our outstanding common stock by a person or group, with limited exceptions;
- each right will entitle the holder, other than an acquiring person, to acquire shares of our common stock at a
  discount to the then prevailing market price;
- our board of directors may redeem outstanding rights at any time prior to a person becoming an acquiring person at a minimal price per right; and
- prior to a person becoming an acquiring person, the terms of the rights may be amended by our board of directors without the approval of the holders of the rights.

Our costs have increased significantly as a result of operating as a public company, and our management is required to devote substantial time to comply with public company regulations.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as new rules subsequently implemented by the SEC and The Nasdaq Global Market, have imposed various new requirements on public companies, including changes in corporate governance practices. The Sarbanes-Oxley Act requires us to maintain effective disclosure controls and procedures and internal controls for financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, significant resources and management oversight are required. Our management and other personnel now devote a substantial amount of time to these new requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

In addition, the Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, commencing in fiscal 2007, we must now perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 requires that we incur substantial expense and expend significant management efforts. If we identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by The Nasdaq Global Market, SEC or other regulatory authorities.

#### We have not paid dividends in the past and do not expect to pay dividends in the future.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all future earnings for the operation and expansion of our business and, therefore, do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends will be at the discretion of our board of directors and will

depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payments of dividends present in our current and future debt agreements, and other factors our board of directors may deem relevant. We are subject to covenants under our debt arrangements that place restrictions on our ability to pay dividends. If we do not pay dividends, a return on your investment will only occur if our stock price appreciates.

#### Item 1B. Unresolved Staff Comments

None

#### Item 2. Properties

Our primary executive and administrative office is located in San Diego, California. We lease 3,465 square feet at this location and the lease expires in February 2011. Our corporate headquarters are located in a 75,626 square foot facility in Rancho Cordova, California. We have leased this facility through August 2009 with an option to renew through August 2024. We conduct a portion of our administrative functions and all of our manufacturing operations at this facility. In early 2006, we moved our research and development, marketing and regulatory operations to a 34,657 square foot facility located on Trade Center Drive in Rancho Cordova, California. We have leased the Trade Center Drive facility through October 2009. Our product distribution operations are located on Mercantile Drive in Rancho Cordova, California. We have leased this 12,960 square foot facility through October 2009. We also lease 4,565 square feet of general office space in Alpharetta, Georgia, from which we conduct U.S. sales administration operations. This lease expires in December 2008. We also lease approximately 950 square feet in San Antonio, Texas for our research and development for our OCT technology. This lease expires in November 2010. Lastly, we currently lease 700 square feet of general office space in Cleveland, Ohio on a month to month basis. This space is occupied by research and development personnel.

In April of 2004 we opened our Japanese sales office concurrently with the creation of our subsidiary, Volcano Japan. We lease 3,660 square feet of office space located in Minato-ku, Tokyo, Japan. This lease expires in March 2009. We conduct our European administrative, sales and product distribution operations through our European subsidiary, Volcano Europe, from 10,894 square feet of leased offices located in Zaventem, Belgium. This lease is non-cancelable through 2007 and expires in 2013. We believe that our current and planned facilities are adequate to meet our needs for the foreseeable future.

#### Item 3. Legal Proceedings

We are not party to any material pending or threatened litigation. We may be subject to various other claims and legal actions arising in the ordinary course of business from time to time.

#### Item 4. Submission of Matters to a Vote of Security Holders

None

#### PART II

# Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

We completed our initial public offering on June 15, 2006. Our Common Stock is traded on the NASDAQ Global Market under the symbol "VOLC". The following table sets forth the high and low sales price of our common stock for the periods indicated.

	Price Range		
	Low		High
Fiscal 2007:			
First Quarter	\$ 16.18	\$	21.87
Second Quarter	17.59		23.10
Third Quarter	14.40		20.97
Fourth Quarter	12.04		19.09
Fiscal Year	12.04		23.10
Fiscal 2006:			
Third Quarter	7.95		14.75
Fourth Quarter	10.52		19.90
Fiscal Year (publicly traded June 15, 2006 through December 31, 2006)	7.90		19.90

As of March 7, 2008, the closing price of our Common Stock on the NASDAQ Global Market was \$11.21 per share, and we had 68 stockholders of record.

Since our incorporation, we have never declared or paid any dividends on our capital stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

On June 15, 2006, we completed an initial public offering of 7,820,000 shares of our common stock, which included 1,020,000 shares sold pursuant to the exercise of the underwriters' over-allotment option. Proceeds from our initial public offering, after deducting offering expenses and underwriting discounts and commissions, were \$54.5 million. Pursuant to a subordinated debt agreement entered into in December 2003, we repaid the outstanding balance of \$29.2 million on our senior subordinated notes, as required, with a portion of the proceeds from our initial public offering. In addition, through December 31, 2007, \$4.6 million was used for other debt repayment, \$11.7 million was used for capital expenditures, \$517,000 was used for the acquisition of intangibles and the remaining \$8.5 million was used to fund a portion of the acquisition of CardioSpectra, Inc.

On December 12, 2006, we completed a follow-on offering of 7,500,000 shares consisting of 3,500,000 shares offered by the Company and 4,000,000 shares offered by certain selling stockholders, including officers of the company. In addition, we sold 795,000 shares under an over-allotment option exercised by the underwriters. The follow-on offering, including the exercise of the over-allotment option, resulted in net proceeds to the Company of \$66.8 million, after deducting offering expenses and underwriting discounts and commissions.

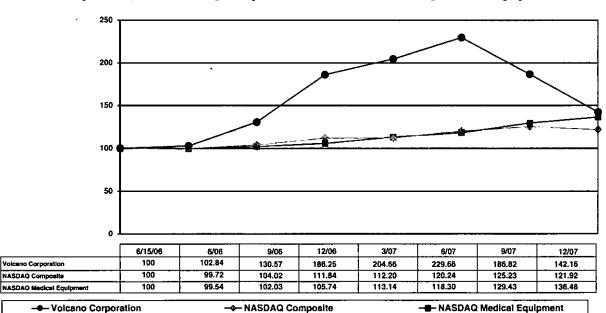
On October 23, 2007, we completed a follow-on offering in which 8,050,000 shares of our common stock were sold by the company, including 1,050,000 shares under an over-allotment option exercised by the underwriters. The follow-on offering, including the exercise of the over-allotment option, resulted in net proceeds to the company of \$122.8 million, after deducting offering expenses and underwriting discounts and commissions.

#### **Performance Graph**

The following Performance Graph and related information shall not be deemed "soliciting material" or "filed" with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

The graph below compares total stockholder return on our common stock from June 15, 2006 (the first day our stock was traded on the NASDAQ Global Market) through December 31, 2007 with the cumulative total return of (a) the NASDAQ Composite Index and (b) the NASDAQ Medical Equipment Index assuming a \$100 investment made in each on June 15, 2006. Each of the three measures of cumulative total return assumes reinvestment of dividends, if any. The stock performance shown on the graph below is based on historical data and is not indicative of, or intended to forecast, possible future performance of our common stock.

Comparison of 18 Month Cumulative Total Return\* Among
Volcano Corporation, The NASDAQ Composite Index And The NASDAQ Medical Equipment Index



#### **Equity Compensation Plan Information**

Information regarding our equity compensation plans is incorporated by reference in Part III, Item 12 of this Annual Report on Form 10-K.

#### **Recent Sales of Unregistered Securities**

None.

#### Recent Purchase of our Registered Equity Securities

We did not purchase any shares of our common stock during the fourth quarter of 2007.

#### **Dividends**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors. None of our outstanding capital stock is entitled to any dividends.

#### Item 6. Selected Financial Data

The selected financial data set forth below are derived from our consolidated financial statements. The consolidated statement of operations data for the years ended December 31, 2007, 2006 and 2005, and the consolidated balance sheet data as of December 31, 2007 and 2006 are derived from our audited consolidated financial statements included elsewhere in this report. The consolidated statement of operations data for the years ended December 31, 2004 and 2003 and the consolidated balance sheet data as of December 31, 2005, 2004 and 2003 are derived from our audited consolidated financial statements which are not included herein.

We were in the developmental stage from our inception in January 2000 until July 2003 when we completed the Jomed Acquisition. We have included the operating results associated with such acquisition in our consolidated financial statements only for the periods since the date of the acquisition in July 2003, which has significantly affected our revenues, results of operations and financial position. Accordingly, our balance sheet and results of operations data presented below for periods prior to the Jomed Acquisition are not comparable to periods subsequent to this acquisition.

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this report (in thousands, except per share data):

	2007	2006	2005	2004	2003
Consolidated Statement of Operations Data:					
Revenues	\$ 130,614	\$ 103,048	\$ 91,900	\$ 61,098	\$ 23,463
Cost of revenues	51,559	41,715	47,843	29,860	14,524
Gross profit	79,055	61,333	44,057	31,238	8,939
Operating expenses:					
Selling, general and administrative	62,631	47,614	35,365	30,374	13,880
Research and development	20,315	16,923	15,119	9,800	8,064
In-process research and					
development <sup>(1)</sup>	26,188	_	_	_	· —
Amortization of intangibles	3,067	3,117	3,052	2,929	1,571
Total operating expenses	112,201	67,654	53,536	43,103	23,515
Operating loss	(33,146)	(6,321)	(9,479)	(11,865)	(14,576)
Interest income	5,841	958	458	153	129
Interest expense	(199)	(4,013)	(5,311)	(4,784)	(565)
Exchange rate gain (loss)	1,452	1,053	(859)	342	(63)
Other, net		18			(16)
Loss before provision for income					
taxes	(26,052)	(8,305)	(15,191)	<u>(16,154</u> )	(15,091)
Provision for income taxes	524	298	70	37	10
Net loss	\$ (26,576)	\$ (8,603)	\$ (15,261)	<u>\$ (16,191)</u>	<u>\$ (15,101)</u>
Net loss per share—basic and diluted	\$ (0.66)	<u>\$ (0.41)</u>	<u>\$ (2.28)</u>	<u>\$ (2.57)</u>	<u>\$ (4.56)</u>
Weighted-average shares outstanding—basic and diluted	40,024	21,113	6,693	6,291	3,312

	As of December 31,									
	_	2007		2006		2005		2004		2003
Balance Sheet Data:										
Cash and cash equivalents <sup>(1)</sup>	\$	122,913	\$	77,738	\$	15,219	\$	11,438	\$	20,398
Short-term available-for-sale investments		66,205		17,787		_				_
Working capital		210,094		108,908		16,993		12,042		21,883
Intangible assets, net <sup>(2)</sup>		9,385		11,946		14,645		17,279		19,739
Total assets		266,574		154,725		68,468		59,141		69,185
Short and long-term debt, including current maturities <sup>(3)</sup>		198		1,720		30,350		34,534		31,286
Convertible preferred stock <sup>(4)</sup>		_				63,060		47,696		47,222
Total stockholders' equity (deficit)		232,937		129,182		(49,468)		(36,976)		(21,526)

These historical results are not necessarily indicative of results expected for any future period.

<sup>(1)</sup> In December 2007, we paid \$25.2 million for the acquisition of CardioSpectra. In connection with this acquisition, we recorded in-process research and development expense of \$26.2 million.

<sup>(2)</sup> Includes the effects of the Jomed Acquisition and the acquisition of other IVUS patents and technology in July 2003 for \$20.7 million.

<sup>(3)</sup> Includes the effects of borrowings under a revolving credit facility commencing in July 2003, the issuance of a note payable in July 2003 of \$3.0 million related to the purchase of certain IVUS patents and technology, the issuance of a \$5.0 million term loan in September 2003 for working capital and general corporate purposes, the issuance of \$20.0 million of senior subordinated notes in December 2003 for working capital and general corporate purposes, the issuance of a \$1.5 million term loan in September 2004 for working capital and general corporate purposes and the issuance of a \$500,000 term loan in March 2005 for working capital and general corporate purposes.

<sup>(4)</sup> Includes the issuance of Series A preferred stock in 2001 in the amount of \$2.3 million, the issuance of Series B preferred stock in 2002 in the amount of \$24.0 million, the issuance of Series B preferred stock and preferred stock warrants in July 2003 in the amount of \$20.1 million and \$321,000, respectively (primarily to finance the Jomed Acquisition), the issuance of Series B preferred stock in November 2003 in the amount of \$500,000, the issuance of Series B preferred stock in March 2004 in the amount of \$250,000, the issuance of Series B preferred stock warrants in 2004 related to debt agreements in the amount of \$224,000, the issuance of Series C preferred stock in February 2005 in the amount of \$15.4 million and the conversion of all outstanding shares of preferred stock into 18,123,040 shares of the Company's common stock in June 2006.

### Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with "Selected Consolidated Financial Data" and our consolidated financial statements and notes thereto included elsewhere in this annual report.

#### Overview

We design, develop, manufacture and commercialize a broad suite of intravascular ultrasound, or IVUS, and functional measurement, or FM, products that we believe enhance the diagnosis and treatment of vascular and structural heart disease. Our products seek to deliver all of the benefits associated with conventional IVUS and FM devices, while providing enhanced functionality and proprietary features that address the limitations associated with conventional forms of these technologies. As a result, we believe that our IVUS and FM products have the potential to become the standard of care to address the needs of patients, hospitals, physicians and third-party payors on a cost-effective basis.

We have focused on building our U.S. and international sales and marketing infrastructure to market our products to physicians and technicians who perform percutaneous interventional procedures in hospitals and to other personnel who make purchasing decisions on behalf of hospitals. We expanded our worldwide sales organization from 60 employees in July 2003 to 137 employees as of December 31, 2007, which included 120 direct sales representatives in the United States, Western Europe and Asia. We sell our products directly to customers in certain European markets and utilize distributors in other European markets, including Spain, Portugal and parts of Italy. As of December 31, 2007, our distribution efforts in Europe were led by a General Manager, a Director of European Sales, 13 account representatives and seven clinical specialists. Three companies distribute our IVUS and FM products in Japan. We have direct contractual relationships with Goodman, Fukuda Denshi and Johnson & Johnson Cordis Division. In addition, Fukuda Denshi has sub-distribution agreements with other parties. While these multi-level relationships allow us to access specific customers and markets, they create complex distribution arrangements and increase our reliance on our Japanese distributors. In emerging markets, including the major markets of Asia Pacific, Latin America, Europe, Australia, Africa and the Middle East, we have distributor relationships through which we sell our products. Our distributors are involved in product launch planning, education and training, physician support and clinical trial management.

Fukuda Denshi, one of our distributors in Japan, accounted for 6.4% of our revenues in 2007, 14.2% in 2006 and 34.5% in 2005. In the first quarter of 2005, Goodman, formerly Boston Scientific's distributor of its IVUS products in Japan, began to distribute our IVUS products in Japan through a sub-distribution agreement with Fukuda Denshi. Due to this new distribution relationship, we experienced a significant increase in orders for our IVUS consoles and catheters from Fukuda Denshi during 2005 as Goodman purchased initial inventory of our products to market to its over 1,100 interventional cardiology accounts. As a result of the significant order activity by Goodman, our revenues, including our mix of consoles and single-procedure disposable catheters, and the costs of those revenues in 2005, may not be comparable to other periods. Additionally, Fukuda Denshi transferred the Japanese regulatory approvals, or shonins, for our phased array IVUS products to us on June 1, 2006. Due to the transfer, we are now able to sell directly to distributors in Japan as opposed to being required to sell our phased array IVUS products only to Fukuda Denshi. As a result, for a portion of 2006, we sold directly to Goodman and Fukuda Denshi and the percentage of our revenues attributable to Fukuda Denshi declined, while the percentage of revenues attributed to Goodman increased, accounting for 18.0%, 15.0% and 1.6% of our revenues for the years ended December 31, 2007, 2006 and 2005.

In 2007, 18.6% of our revenues and 11.5% of our operating expenses were denominated in foreign currencies. As a result, we are subject to risks related to fluctuations in foreign currency exchange rates, which could affect our operating results in the future.

Our IVUS products are comprised of consoles, single-procedure disposable catheters and advanced functionality options. Our family of consoles includes the IVUS In-Vision Gold, or IVG, and the new PC-based s5. The s5 family of products was launched on a limited basis early in 2006 and became our primary console offering following its full commercial launch in mid-2006. We are developing advanced functionality options including real-time VH IVUS, IVUS and angiographic image co-registration, and phased array and rotational catheter compatibility. Our single-procedure disposable IVUS catheters only operate and interface with our family of IVUS consoles.

Our FM products consist of pressure and flow consoles and single-procedure disposable pressure and flow guide wires. Our FM consoles are mobile, proprietary and high speed electronic systems with different functionalities and sizes designed and manufactured to process and display the signals received from our guide wires.

We are developing customized cath lab versions of our consoles and advanced functionality options as part of our vfusion cath lab integration initiative. The significantly expanded functionality of our vfusion offering will allow for networking of patient information, control of IVUS and FM information at both the operating table and in the cath lab control room, as well as the capability for images to be displayed on standard cath lab monitors. We expect to continue to develop new products and technologies to expand our vfusion offering.

As of December 31, 2007, we had a worldwide installed base of over 2,400 IVUS consoles and over 800 FM consoles. We intend to grow and leverage this installed base to drive recurring sales of our single-procedure disposable catheters and guide wires. In 2007, the sale of our single-procedure disposable catheters and guide wires accounted for \$97.8 million, or 74.9% of our revenues, a \$21.5 million, or 28.1% increase from 2006, in which the sale of our single-procedure disposable catheters and guide wires accounted for \$76.3 million, or 74.1% of our revenues.

We manufacture our IVUS and FM consoles, IVUS catheters and FM guide wires at our facility in Rancho Cordova, California. We use third-party manufacturing partners to produce circuit boards and mechanical sub-assemblies used in the manufacture of our consoles. We also use third-party manufacturing partners for certain proprietary components used in the manufacture of our single-procedure disposable products. We perform incoming inspection on these circuit boards, mechanical sub-assemblies and components, assemble them into finished products, and test the final product to assure quality control. Our former supplier of FM wire pressure sensors ceased production of this key component on 4" wafers. We secured an end-of-life purchase in 2007 of the subject parts equivalent to an estimated four-year supply. We believe this will provide us with adequate time to initiate and qualify a replacement supplier or a new design to replace the product. We expect that it will take approximately 24 months to identify an appropriate replacement supplier, complete design work and undertake the necessary inspections before the new pressure sensors will be available.

From our inception in January 2000 until July 2003, we were engaged principally in the research and development of tools designed to diagnose vulnerable plaque. In July 2003, we purchased substantially all of the assets and assumed certain liabilities associated with the IVUS and FM product lines of Jomed, Inc., or the Jomed Acquisition. We also acquired certain IVUS patents and technology from Philips in July 2003. These purchases were significant in executing our strategy to leverage our IVUS technology and build our business. Our revenues have increased from \$91.9 million in 2005 to \$103.0 million in 2006 to \$130.6 million in 2007. Our operating loss decreased from \$9.5 million in 2005 to \$6.3 million in 2006, but increased to \$33.1 million in 2007, which included a \$26.2 million charge related to in-process research and development acquired as part of the acquisition of CardioSpectra. At December 31, 2007, our accumulated deficit was \$90.6 million. Since our inception, we have not been profitable for a full fiscal year, and we expect to continue to incur net losses for the foreseeable future.

In March 2006, we entered into a supply and distribution agreement with GE, pursuant to which we are collaborating on the development and distribution of our s5i GE Innova product, which is our IVUS imaging system console that is installed directly into a cath lab on a permanent basis and is able to be integrated with GE's Innova system. Under the terms of the agreement, GE has been granted exclusive distribution rights worldwide, excluding Japan, for the s5i GE Innova product for a period of 12 months, subject to minimum purchase forecasts, and non-exclusive distribution rights thereafter. The 12-month exclusivity period ended on August 15, 2007, after which, GE had non-exclusive distribution rights worldwide, excluding Japan, for our s5i product. Unless extended, or terminated earlier in accordance with its terms, the agreement will expire on December 31, 2009. GE's obligation to purchase products from us under the agreement is limited to firm purchase orders made by GE and accepted by us. No minimum purchase requirements are required and the forecasts to be provided under the agreement will not be binding. While we have not previously entered into a distribution arrangement that is similar to our agreement with GE, we believe our relationship with GE will enable us to increase sales of our consoles worldwide, excluding Japan.

We completed an underwritten initial public offering on June 15, 2006 in which we sold 7,820,000 shares of our common stock to the public at an offering price of \$8.00 per share. The initial public offering resulted in net proceeds of \$54.5 million, after deducting offering expenses and underwriting discounts and commissions.

On December 12, 2006, we completed an underwritten follow-on offering in which 3,500,000 shares of our common stock were sold by the company and 4,000,000 shares were sold by certain selling stockholders, including officers of the company. In addition, we sold 795,000 shares under an over-allotment option exercised by the underwriters. The follow-on offering, including the exercise of the over-allotment option, resulted in net proceeds to the Company of \$66.8 million, after deducting offering expenses and underwriting discounts and commissions.

On October 23, 2007, we completed an underwritten follow-on offering in which 8,050,000 shares of our common stock were sold by the company, including 1,050,000 shares under an over-allotment option exercised by the underwriters. The follow-on offering, including the exercise of the over-allotment option, resulted in net proceeds to the company of \$122.8 million, after deducting offering expenses and underwriting discounts and commissions.

On December 18, 2007, we acquired CardioSpectra, a company founded in 2005 and based in San Antonio, Texas. CardioSpectra's core product line is based on technology licensed from the University of Texas and Dr. Thomas Milner, a co-founder of CardioSpectra. Through CardioSpectra, we are developing innovative Optical Coherence Tomography (OCT) technology, which is expected to complement our existing product offerings and further enhance our position as an imaging technology leader in the field of interventional medicine.

#### Financial Operations Overview

The following is a description of the primary components of our revenue and expenses.

Revenues. We derive our revenues primarily from the sale of our IVUS and FM consoles and single-procedure disposables. In 2007, 86.0% of our revenues were derived from the sale of our IVUS consoles and IVUS single-procedure disposables, as compared with 85.8% in 2006 and 84.5% in 2005. In 2007, 74.9% of our revenues were derived from the sale of our IVUS and FM single-procedure disposables, as compared with 74.1% in 2006 and 70.4% in 2005. Other revenues consist primarily of spare parts sales, service and maintenance revenues, shipping and handling revenues and license fees from Medtronic, Inc. and certain of its affiliates, or Medtronic, a related party.

Our sales in the United States are generated by our direct sales representatives and our products are shipped and billed to hospitals throughout the United States from our facility in Rancho Cordova, California. Our international sales are generated by our direct sales representatives or through independent distributors and are shipped and billed throughout the world from our facilities in Rancho Cordova, California, Zaventem, Belgium and Chiba, Japan.

We experienced a significant increase in our revenues from 2007 compared with 2006, with year-over-year growth evident in all product categories and all regions.

We expect to experience variability in our quarterly revenues from IVUS and FM consoles due to the timing of hospital capital equipment purchasing decisions, a condition which is inherent in our industry. Further, we expect variability of our revenues based on the timing of our new product introductions which may cause our customers to delay their purchasing decisions until the new products are commercially available. Alternatively, we may include in our arrangements with customers an obligation to deliver new products which are not yet commercially available. In these cases, we would be required to defer associated revenues from these customers until we have met our delivery obligations.

Cost of Revenues. Cost of revenues consists primarily of material costs for the products that we sell and other costs associated with our manufacturing process such as personnel costs, rent and depreciation. In addition, cost of revenues includes royalty expenses for licensed technologies included in our products, service costs, provisions for warranty, distribution, freight and packaging costs and stock compensation expense. We expect our gross margin to improve if we are able to complete our ongoing efforts to streamline and improve our manufacturing processes and increase production volumes.

Selling, General and Administrative. Selling, general and administrative expenses consist primarily of salaries and other related costs for personnel serving the sales, marketing, executive, finance, information technology and

human resource functions. Other costs include travel and entertainment expenses, facility costs, trade show, training and other promotional expenses, professional fees for legal and accounting services and stock compensation expense. We expect that our selling, general and administrative expenses will increase as we continue to expand our sales force and marketing efforts and invest in the necessary infrastructure to support our continued growth.

**Research and Development.** Research and development expenses consist primarily of salaries and related expenses for personnel, consultants, prototype materials, clinical studies, depreciation, regulatory filing fees, certain legal costs related to our intellectual property and stock compensation expense. We expense research and development costs as incurred. We expect our research and development expenses to increase as we continue to develop our products and technologies.

Amortization of Intangibles. Intangible assets, which consist of our developed technology, licenses, customer relationships, patents and trademarks, are amortized using the straight-line method over their estimated useful lives ranging from three to ten years.

Interest Income. Interest income is comprised of interest income earned from our cash and cash equivalents, short-term available-for-sale investments.

*Interest Expense.* Interest expense is comprised primarily of interest expense on short-term debt and term loans. We expect interest expense in 2008 to decrease as we plan to continue to pay down our existing loan balances.

Exchange Rate Gain (Loss). Exchange rate gain (loss) is comprised of foreign currency transaction gains and losses.

Provision for Income Taxes. Provision for income taxes is comprised of state, local and foreign income taxes.

Due to uncertainty surrounding the realization of deferred tax assets through future taxable income, we have provided a full valuation allowance and no current benefit has been recognized for the net operating loss and other deferred tax assets. Accordingly, deferred tax asset valuation allowances have been established as of December 31, 2007, 2006 and 2005 to reflect these uncertainties. The federal net operating loss carryforwards begin to expire in 2020, the state net operating loss carryforwards begin to expire in 2012 and the foreign net operating loss carryforwards begin to expire in 2009, unless these net operating losses are previously utilized. We also have federal research and experimentation tax credits, which begin to expire in 2022, and state research and experimentation tax credits, which carry forward indefinitely. Use of our net operation loss carryforwards may be limited if cumulative change in ownership of more than 50% has occurred within a rolling three-year period.

### **Results of Operations**

The following table sets forth items derived from our consolidated statements of operations for the years ended December 31, 2007, 2006 and 2005 presented in both absolute dollars (in thousands) and as a percentage of revenues:

		Ye	ears Ended Dece	mber 31,		
	2007	<u>-</u>	2006		2005	
Revenues	\$ 130,614	100.0% \$	103,048	100.0%	91,900	100.0%
Cost of revenues	51,559	39.5	41,715	40.5	47,843	52.1
Gross profit	79,055	60.5	61,333	59.5	44,057	47.9
Operating expenses:						
Selling, general and administrative	62,631	48.0	47,614	46.2	35,365	38.5
Research and development	20,315	15.6	16,923	16.4	15,119	16.4
In-process research and development	26,188	20.0		_	_	
Amortization of intangibles	3,067		3,117	3.0	3,052	3.3
Total operating expenses	112,201	85.9	67,654	65.6	53,536	58.2
Operating loss	(33,146)	(25.4)	(6,321)	(6.1)	(9,479)	(10.3)
Interest income	5,841	4.5	958	0.9	458	0.5
Interest expense	(199)	(0.2)	(4,013)	(3.9)	(5,311)	(5.8)
Exchange rate gain (loss)	1,452	1.1	1,053	1.0	(859)	(0.9)
Other, net	<u> </u>		18	0.0		
Loss before provision for income taxes	(26,052)	(19.9)	(8,305)	(8.1)	(15,191)	(16.5)
Provision for income taxes	524	0.4	298	0.3	70	0.1
Net loss	<u>\$ (26,576)</u>	(20.3)% \$	(8,603)	(8.3)%	<u>\$ (15,261)</u>	(16.6)%

The following table sets forth our revenues by geography expressed as dollar amounts (in thousands) and the changes in revenues between the specified periods expressed as percentages:

	Years Ended December 31,										
		2007		2006	Percentage Change 2006 to 2007		2005	Percentage Change 2005 to 2006			
Revenues <sup>(1)</sup> :											
United States	\$	66,411	\$	51,013	30.2%	\$	40,933	24.6%			
Japan		35,186		30,082	17.0%		33,207	(9.4)%			
Europe, the Middle East and											
Africa		23,995		17,765	35.1%		15,294	16.2%			
Rest of world		5,022		4,188	19.9%	_	2,466	69.8%			
	\$	130,614	\$	103,048	26.8%	<u>\$</u>	91,900	12.1%			

<sup>(1)</sup> Revenues are attributed to geographies based on location of the customer, except for original equipment manufacturer revenues which are attributed to the geography of the legal entity invoicing.

The following table sets forth our revenues by product expressed as dollar amounts (in thousands) and the changes in revenues between the specified periods expressed as percentages:

Years Ended December 31,											
		2007		2006	Percentage Change 2006 to 2007	2005		Percentage Change 2005 to 2006			
IVUS:				•							
Consoles	\$	26,847	\$	22,128	21.3%	\$	23,617	(6.3)%			
Single-procedure disposables		85,537		66,268	29.1%		54,069	22.6%			
FM:											
Consoles		2,064		1,954	5.7%		1,394	40.1%			
Single-procedure disposables		12,260		10,072	21.7%		10,635	(5.3)%			
Other	_	3,905	_	2,626	48.7%	_	2,185	20.2%			
	\$	130,614	\$	103,048	26.8%	<u>\$</u>	91,900	12.1%			

#### Comparison of Years Ended December 31, 2007 and 2006

Revenues. Revenues increased \$27.6 million, or 26.8%, to \$130.6 million in 2007, as compared to revenues of \$103.0 million in 2006. In 2007, a large part of our growth in revenues was derived from our IVUS disposable products with a \$19.3 million increase in revenues attributable to higher sales volume of our single-procedure disposable IVUS products. We attribute the increase in IVUS disposable revenue to increased market penetration of IVUS in interventional procedures and gains in our market share world-wide. Additionally, for the year ended December 31, 2007, IVUS console revenue increased \$4.7 million, or 21.3%, as compared with the same period in 2006. The increase in IVUS console revenue resulted primarily from an increase in the number of consoles sold. Increases in revenues were realized across all geographies.

Cost of Revenues. Cost of revenues increased \$9.8 million, or 23.6%, to \$51.6 million, or 39.5% of revenues in 2007, from \$41.7 million, or 40.5% of revenues in 2006. Gross margin was 60.5% of revenues in 2007 as compared to 59.5% of revenues in 2006. The increase in gross margin percentage is largely due to an increase in the average selling price and a decrease in production cost of certain IVUS catheters, as well as an increase in the average selling prices for certain FM disposables. These factors were partially offset by average selling price reductions of s5i IVUS consoles, higher warranty expense and higher shipping expense.

Selling, General and Administrative. Selling, general and administrative expenses increased \$15.0 million, or 31.5%, to \$62.6 million, or 48.0% of revenues in 2007, as compared to \$47.6 million, or 46.2% of revenues in 2006. The increase in 2007 as compared with 2006 is a result of higher payroll related costs due to increased headcount, higher stock compensation expense, higher marketing expenses, primarily related to attendance at trade shows, and new product launches, and an increase in corporate expenditures, including costs associated with our reporting obligations as a public company, including compliance with Sarbanes-Oxley.

**Research and Development.** Research and development expenses increased \$3.4 million, or 20.0%, to \$20.3 million, or 15.6% of revenues in 2007, as compared to \$16.9 million, or 16.4% of revenues in 2006. The increase in research and development expenses in 2007 was due to higher payroll related costs associated with increased headcount, higher material costs related to increased consumption, higher clinical trial expenses, higher regulatory expenses primarily related to product introductions in Japan and higher stock compensation expense.

In-process Research and Development. In-process research and development was \$26.2 million in 2007 and relates to our acquisition of CardioSpectra.

Amortization of Intangibles. Amortization expense was relatively unchanged at \$3.1 million, or 2.3% of revenues in 2007, as compared to \$3.1 million, or 3.0% of revenues in 2006.

*Interest Expense.* Interest expense decreased \$3.8 million, or 95.0%, to \$200,000, or 0.2% of revenues in 2007, as compared to \$4.0 million, or 3.9% of revenues in 2006. The decrease in interest expense in 2007 as compared to 2006 was attributable to lower average debt balances. Our average debt balances decreased primarily due to the

repayment of \$29.2 million of our senior subordinated debt and the repayment of \$750,000 of our short-term debt in 2006.

Interest and Other Income (Expense), Net. Interest and other income (expense), net was income of \$7.3 million in 2007, as compared to \$2.0 million in 2006. The change in 2007 as compared to 2006 was primarily attributable to a gain of \$1.5 million on foreign exchange transactions in 2007 as compared to \$1.1 million in 2006, and by higher interest income, earned on our cash and cash equivalents and short-term available-for-sale investments, of \$5.8 million in 2007 as compared to \$958,000 in 2006.

### Comparison of Years Ended December 31, 2006 and 2005

Revenues. Revenues increased \$11.1 million, or 12.1%, to \$103.0 million in 2006, as compared to revenues of \$91.9 million in 2005. In 2006, substantially all of our growth in revenues was derived from our IVUS disposable products with a \$12.2 million increase in revenues attributable to higher sales volume of our single-procedure disposable IVUS products, partially offset by a \$1.5 million decrease in IVUS console sales. Increases in revenues were realized across all geographies. We attribute the increase in IVUS disposable revenue to increased market penetration of IVUS in interventional procedures and gains in our market share world-wide. The decrease in IVUS consoles in 2006 was due to a higher volume of console sales to Goodman in 2005, following the initiation of the sub-distribution agreement by and among Fukuda Denshi, Goodman and us in the first quarter of 2005.

Cost of Revenues. Cost of revenues decreased \$6.1 million, or 12.8%, to \$41.7 million, or 40.5% of revenues in 2006, from \$47.8 million, or 52.1% of revenues in 2005. The decrease in cost of revenues in 2006 was partially due to the absence of a \$3.4 million charge in the fourth quarter of 2005 related to the write-down of IVUS IVG console inventory and related assets. During the fourth quarter of 2005, we announced the upcoming release of our new s5 family of IVUS consoles to occur in 2006. In conjunction with the proposed new product introduction, we performed an assessment of the valuation of the inventory and other assets, including long-lived assets, associated with the IVUS IVG console. As a result, during the fourth quarter of 2005, we recorded write-downs for the excess and obsolete IVUS IVG inventory of \$963,000, impairment of IVUS IVG diagnostic equipment in the amount of \$360,000 and accruals related to future non-cancelable IVUS IVG inventory purchase commitments of \$2.0 million. The decrease in the cost of revenues was also due to a shift away from the lower margin IVG IVUS consoles to the higher margin s5 IVUS consoles.

Gross margin was 59.5% of revenues in 2006 as compared to 47.9% of revenues in 2005. The increase in gross margin is due to the \$3.4 million charge in the fourth quarter of 2005 relating to the IVUS IVG product line and increased sales of higher margin s5 consoles in 2006.

Selling, General and Administrative. Selling, general and administrative expenses increased \$12.2 million, or 34.6%, to \$47.6 million, or 46.2% of revenues in 2006, as compared to \$35.4 million, or 38.5% of revenues in 2005. The increase in 2006 as compared with 2005 is a result of higher payroll related costs due to increased headcount, an increase in corporate expenditures, including costs associated with our reporting obligations as a public company, increased facility and information technology expense, marketing expenses, primarily related to attendance at trade shows, and new product launches and higher stock compensation expense as a result of adopting SFAS No. 123(R) on January 1, 2006.

Research and Development. Research and development expenses increased \$1.8 million, or 11.9%, to \$16.9 million, or 16.4% of revenues in 2006, as compared to \$15.1 million, or 16.4% of revenues in 2005. The increase in research and development expenses in 2006 was due to higher payroll related costs associated with increased headcount, higher material costs related to increased consumption and higher regulatory expenses primarily related to product introductions in Japan.

Amortization of Intangibles. Amortization expense was relatively unchanged at \$3.1 million, or 3.0% of revenues in 2006, as compared to \$3.1 million, or 3.3% of revenues in 2005.

Interest Expense. Interest expense decreased \$1.3 million, or 24.4%, to \$4.0 million, or 3.9% of revenues in 2006, as compared to \$5.3 million, or 5.8% of revenues in 2005. The decrease in interest expense in 2006 as compared to 2005 was attributable to lower average debt balances. Our average debt balances decreased primarily due to the repayment of \$29.2 million of our senior subordinated debt and the repayment of \$750,000 of our short-term debt in

2006. Partially offsetting the lower interest expense was a \$1.2 million charge in 2006 related to the expensing of unamortized debt discount and deferred financing fees, which resulted from the repayment of our senior subordinated notes in connection with our initial public offering.

Interest and Other Income (Expense), Net. Interest and other income (expense), net was income of \$2.0 million in 2006, as compared to an expense of \$401,000 in 2005. The change in 2006 as compared to 2005 was primarily attributable to a gain of \$1.1 million on foreign exchange transactions in 2006 as compared to a loss of \$859,000 in 2005, and by higher interest income, earned on our cash and cash equivalents and short-term available-for-sale investments, of \$958,000 in 2006 as compared to \$458,000 in 2005.

#### Liquidity and Capital Resources

#### Sources of Liquidity

At December 31, 2007, our cash and cash equivalents and short-term available-for-sale investments totaled \$189.1 million. We invest our excess funds in short-term securities issued by corporations, banks, municipalities and financial holding companies and in money market funds comprised of these same types of securities.

On June 15, 2006, we completed an underwritten initial public offering of 7,820,000 shares of our common stock, which included 1,020,000 shares sold pursuant to the exercise of the underwriters' over-allotment option. Proceeds of the offering, after deducting offering expenses and underwriting discounts and commissions were \$54.5 million. Pursuant to a subordinated debt agreement entered into in December 2003, we repaid the outstanding balance of \$29.2 million on our senior subordinated notes, as required, with a portion of the proceeds from our initial public offering. In addition, through December 31, 2007, \$4.6 million was used for other debt repayment, \$11.7 million was used for capital expenditures and \$517,000 was used for the acquisition of intangibles. The remaining net proceeds were used to help fund a portion of the acquisition of CardioSpectra in December 2007.

On December 12, 2006, we completed a follow-on underwritten public offering in which 3,500,000 shares of our common stock were sold by the company and 4,000,000 shares were sold by certain selling stockholders, including officers of the company. In addition, we sold 795,000 shares under an over-allotment option exercised by the underwriters. The follow-on offering, including the exercise of the over-allotment option, resulted in net proceeds to the Company of \$66.8 million, after deducting offering expenses and underwriting discounts and commissions.

On October 23, 2007, we completed a follow-on offering in which 8,050,000 shares of our common stock were sold by the company, including 1,050,000 shares under an over-allotment option exercised by the underwriters. The follow-on offering, including the exercise of the over-allotment option, resulted in net proceeds to the company of \$122.8 million, after deducting offering expenses and underwriting discounts and commissions.

At December 31, 2007, our accumulated deficit was \$90.6 million. Since inception, we have generated significant operating losses and as a result we did not generate sufficient cash flow to fund our operations and the growth in our business. Accordingly, prior to our initial public offering, we financed our operations and acquisitions primarily through the issuances of \$62.5 million of preferred stock, \$20.0 million of senior subordinated notes and \$7.0 million of term loans. These issuances of equity and debt were supplemented with borrowings from our revolving credit facility and equipment financing arrangements. In addition, in July 2003, we financed a portion of our acquisition of certain IVUS patents and technology by entering into a non-interest bearing note with Philips in the amount of \$3.3 million. The issuances of our senior subordinated notes, term loans and our revolving credit facility included warrants to purchase our Series B preferred stock, which automatically converted into warrants to purchase common stock upon the completion of our initial public offering, or our common stock. In May 2007 our revolving credit facility expired as scheduled.

We are subject to several covenants that place restrictions on our ability to incur additional debt and liens, pay dividends and sell or dispose of any of our assets outside the normal course of business. We are in compliance with all covenants and limitations included in the provisions of our loan agreements as of December 31, 2007.

#### Cash Flows

Cash Flows from Operating Activities. Cash provided by operating activities of \$4.2 million for 2007 reflected our net loss of \$26.6 million, non-cash investment accretion of \$1.2 million and a gain on foreign exchange of \$1.5 million. In addition, accounts receivable increased \$5.8 million, inventory increased \$7.7 million and prepaid expenses and other current assets increased \$1.9 million. The increase in accounts receivable is due to the increased sales volume and timing of cash receipts, the increase in inventory is due to anticipated increased sales volume and the increase in prepaid expenses and other current assets is primarily due to payments made for future expenses. These amounts were offset by non-cash expenses consisting of a write off of in-process research and development of \$26.2 million related to the acquisition of CardioSpectra, depreciation and amortization of \$7.9 million and non-cash stock compensation expense of \$6.8 million. In addition, accounts payable increased \$2.2 million related to the increase in inventory and timing of payments, accrued compensation increased \$3.0 million, primarily due to increased headcount and salary deferrals for the employee stock purchase plan, and deferred revenue increased \$2.4 million.

Cash used in operating activities of \$3.4 million for 2006 reflected our net loss of \$8.6 million and a non-cash gain on foreign exchange of \$1.1 million, offset by adjustments for non-cash expenses consisting primarily of depreciation and amortization of \$8.5 million, interest capitalized as debt principal of \$2.0 million, stock compensation expense of \$3.2 million and the amortization and write-off of debt discount and deferred financing fees of \$1.8 million. In addition, accounts receivable increased \$5.1 million, inventory increased \$3.0 million, and accounts payable decreased \$2.7 million. These uses of cash are due to the timing of cash receipts and payments, as well as the increase in sales and manufacturing activity. These uses of cash were partially offset by a \$1.5 million increase in accrued compensation expense resulting from an increase in accrued commissions, as a result of higher sales, and increased relocation costs.

Cash provided by operating activities of \$2.6 million for 2005 reflected our net loss of \$15.3 million, offset by adjustments for non-cash expenses consisting primarily of depreciation and amortization of \$7.1 million, interest capitalized as debt principal of \$3.8 million and stock compensation expense of \$1.9 million. In addition, accounts receivable increased \$4.1 million and inventories increased \$2.7 million reflecting higher sales and manufacturing activity in 2005, as well as purchases of components for new product introductions. These uses of cash were offset by an increase in accounts payable and accrued liabilities of \$9.9 million, resulting from the higher sales and manufacturing activity in 2005, as well as purchases of components for new product introductions, higher accrued compensation costs reflecting continued growth in our employee headcount, and a \$2.0 million accrual for losses on non-cancelable IVUS IVG inventory purchase commitments.

Cash Flows from Investing Activities. Cash used in investing activities was \$81.6 million in 2007, \$23.2 million in 2006 and \$6.0 million in 2005. In 2007, \$105.8 million was used to purchase short-term available-for-sale securities, \$25.2 million was used to purchase CardioSpectra and \$9.1 million was used for purchases of long term assets including capital expenditures for medical diagnostic equipment and manufacturing equipment. These purchases were partially offset by \$58.6 million from the sale or maturity of short-term available-for-sale investments. In 2006, \$17.9 million was used to purchase short-term available-for-sale investments and \$5.3 million was primarily related to purchases of long term assets, including capital expenditures for medical diagnostic equipment and manufacturing equipment. Cash used in investing activities during 2005 was primarily related to capital expenditures for medical diagnostic equipment, manufacturing equipment, the upgrade of our computer system and the expansion of our manufacturing and research and development facilities.

Cash Flows from Financing Activities. Cash provided by financing activities was \$122.7 million in 2007, \$89.1 million in 2006 and \$7.3 million in 2005. Cash provided by financing activities in 2007 consisted primarily of \$122.8 million in proceeds from our underwritten follow-on public offering. Cash provided by financing activities in 2006 consisted primarily of the \$121.3 million in net proceeds from our initial public offering and follow-on offering, partially offset by repayment of debt of \$32.4 million. Net cash provided by financing activities in 2005 consisted primarily of proceeds from the sale of preferred stock, the issuance of debt and the sale of common stock, partially offset by the repayment of debt.

#### Future Liquidity Needs

Our future liquidity and capital requirements will be influenced by numerous factors, including the extent and duration of future operating losses, the level and timing of future sales and expenditures, the results and scope of ongoing research and product development programs, working capital required to support our sales growth, the receipt of and time required to obtain regulatory clearances and approvals, our sales and marketing programs, the continuing acceptance of our products in the marketplace, competing technologies and market and regulatory developments. As of December 31, 2007, we believe our current cash and cash equivalents and our short-term available-for-sale investments will be sufficient to fund working capital requirements, capital expenditures, and operations for at least the next 12 months. We intend to retain any future earnings to support operations and to finance the growth and development of our business, and we do not anticipate paying any dividends in the foreseeable future.

Our ability to fund our longer-term cash needs is subject to various risks, many of which are beyond our control See—"Risk Factors." Should we require additional funding, such as additional capital investments, we may need to raise the required additional funds through bank borrowings or public or private sales of debt or equity securities. We cannot assure that such funding will be available in needed quantities or on terms favorable to us.

As of December 31, 2007, we have federal and state net operating loss carryforwards of \$48.0 million and \$25.0 million, respectively, available to reduce future taxable income if we become profitable. We expect to utilize our available net operating loss carryforwards to reduce future tax obligations in the event we are successful in achieving profitability. However, limitations on our ability to use net operating loss carryforwards and other minimum state taxes may increase our overall tax obligations.

#### Off-Balance Sheet Arrangements and Other Contractual Obligations

In conjunction with the sale of our products in the ordinary course of business, we provide standard indemnification to business partners and customers for losses suffered or incurred for patent, copyright or any other intellectual property infringement claims by any third parties with respect to our products. The term of these indemnification arrangements is generally perpetual. The maximum potential amount of future payments we could be required to make under these agreements is unlimited. As of December 31, 2007, we have not incurred any costs to defend lawsuits or settle claims related to these indemnification arrangements.

The following table summarizes our significant contractual obligations and commercial commitments as of December 31, 2007 for each of the periods indicated (in thousands):

	Payment Due By Period									
Contractual Obligations and Commercial Commitments		Total	Less Than 1 Year			1-3 Years		3-5 Years		Aore than Years
Debt	\$	64	\$	64	\$	_	\$	_	\$	
Interest on debt(1)		1		1		_		_		
Capital lease obligations (including interest)		146		64		80		2		_
Operating lease obligations(2)		4,212		2,349		1,863				_
Minimum payments under license agreements(3)		1,835		755		780		50		250
Non-cancelable purchase commitments(4)		9,885		9,885					_	
Total(5)	\$	16,143	<u>\$</u>	13,118	<u>\$</u>	2,723	\$	52	\$	250

<sup>(1)</sup> Future interest payments on our debt are based on the assumption that the debt is outstanding until maturity and all interest expense has been calculated for all future periods using the rate implicit in the respective debt agreements.

<sup>(2)</sup> We lease office space and have entered into other lease commitments in the United States as well as locations in Europe and Asia. Operating lease obligations include future minimum lease payments under all our non-cancelable operating leases as of December 31, 2007.

- (3) Our license agreements include provisions that require us to make milestone or royalty payments to the licensor based on the amount of future sales of covered products. Certain of these agreements require that the royalties we pay in a given year total at least a minimum amount as set forth in the agreements. The royalty obligations we may incur in excess of these minimum amounts are not included in the table above because we cannot, at this time, determine the timing or amount of these obligations.
- (4) Consists of non-cancelable commitments primarily for the purchase of production materials.
- (5) The table above does not include potential milestone payments up to an aggregate of \$38 million due to the former shareholders of CardioSpectra (see "Acquisitions" note to our consolidated financial statements).

#### **Critical Accounting Policies**

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses.

Critical accounting policies are those that are both important to the portrayal of our financial condition and results of operations and require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. As the number of variables and assumptions affecting the possible future resolution of the uncertainties increase, those judgments become even more subjective and complex. In order to provide an understanding about how our management forms its judgments about future events, including the variables and assumptions underlying the estimates, and the sensitivity of those judgments to different circumstances, we have identified our critical accounting policies below.

Revenue Recognition. We recognize revenues in accordance with Staff Accounting Bulletin, or SAB, No. 104 when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectibility is reasonably assured. Revenue from the sale of our products is generally recognized when title and risk of loss transfers to the customer upon shipment, the terms of which is generally free on board shipping point. We use contracts and customer purchase orders to determine the existence of an arrangement. We use shipping documents and third-party proof of delivery to verify that title has transferred. We assess whether the fee is fixed or determinable based upon the terms of the agreement associated with the transaction. To determine whether collection is probable, we assess a number of factors, including past transaction history with the customer and the creditworthiness of the customer.

We frequently enter into sales arrangements with customers that contain multiple elements or deliverables, and for these we apply the provisions of Emerging Issues Task Force, or EITF, Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. We are required to make judgments which impact the timing and amount of revenue recognized in a given period. For example, because the sale of our products and services are often contemplated in a single arrangement, we make judgments as to the allocation of the proceeds received from the arrangement to the multiple elements of the arrangement, the determination of whether any undelivered elements are essential to the functionality of the delivered elements and the appropriate timing of revenue recognition. In addition, our ability to establish and maintain objective and reliable evidence of fair value for the elements in our arrangements could affect the timing of revenue recognition. The elements of a typical revenue arrangement can include a console, options for the console, single-procedure disposable products and a service and maintenance agreement.

We occasionally enter into agreements requiring cash payments to partners who are also customers. We apply the provisions of EITF 01-09, Accounting for Consideration Given by a Vendor to a Customer, to account for cash payments made under these agreements.

Inventory Valuation. We state our inventories at the lower of cost or market value, determined on a first-in, first-out basis. We provide inventory allowances when conditions indicate that the selling price could be less than cost due to obsolescence and reductions in estimated future demand. We balance the need to maintain strategic inventory levels with the risk of obsolescence due to changing technology and customer demand levels. Unfavorable changes in market conditions may result in a need for additional inventory reserves that could adversely impact our gross margins. Conversely, favorable changes in demand could result in higher gross margins when we sell products.

Valuation of Long-lived Assets. Our long-lived assets consist of property and equipment and intangible assets. Equipment is carried at cost and is depreciated over the estimated useful lives of the assets, which are generally three to five years, and leasehold improvements are amortized over the lesser of the lease term or the estimated

useful lives of the improvements, which is between three and ten years. The straight-line method is used for depreciation and amortization. Intangible assets primarily consist of developed technology, customer relationships, licenses, and patents and trademarks, which are amortized using the straight-line method over periods ranging from three to ten years, representing the estimated useful lives of the assets. We capitalize external legal costs and filing fees associated with obtaining patents on our new discoveries and amortize these costs using the straight-line method over the shorter of the legal life of the patent or its economic life, generally ten years. Acquired intellectual property is recorded at cost and is amortized over its estimated useful life. We believe the useful lives we assigned to these assets are reasonable.

We consider no less frequently than quarterly whether indicators of impairment of long-lived assets are present. These indicators may include, but are not limited to, significant decreases in the market value of an asset and significant changes in the extent or manner in which an asset is used. If these or other indicators are present, we determine whether the estimated future undiscounted cash flows attributable to the assets in question are less than their carrying value. If less than their carrying value, we recognize an impairment loss based on the excess of the carrying amount of the assets over their respective fair values. Fair value is determined by discounted future cash flows, appraisals or other methods.

The evaluation of asset impairments relative to long-lived assets require us to make assumptions about future cash flows over the life of the asset being evaluated which requires significant judgment. Actual results may differ from assumed or estimated amounts.

Stock-based Compensation. Effective January 1, 2006, we began accounting for share-based awards under the provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment, or SFAS No. 123(R), which requires the recognition of the fair value of stock-based compensation. Under the fair value recognition provisions of SFAS No. 123(R), stock-based compensation cost is estimated at the grant date based on the fair value of the awards expected to vest and recognized as expense ratably over the requisite service period of the award.

We adopted SFAS No. 123(R) using the modified prospective method which requires the application of the accounting standard as of January 1, 2006. Our consolidated financial statements as of and for the year ended December 31, 2006 reflect the impact of SFAS No. 123(R). In accordance with the modified prospective method, the consolidated financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123(R).

Prior to January 1, 2006, we used the intrinsic method of accounting for employee stock options under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, or APB No. 25, and presented disclosure of pro forma information required under SFAS No. 123, Accounting for Stock-Based Compensation, as amended by SFAS No. 148, Accounting for Stock-Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123, or SFAS No. 148. For stock options granted to employees under APB No. 25, no compensation expense was recognized unless the exercise price was less than the estimated fair market value at the date of grant. We apply the provisions of EITF No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services, and use the Black-Scholes option pricing model to determine the fair value of each option grant to non-employees. See "Stockholders' Equity (Deficit)" note to our consolidated financial statements.

The fair value of the common stock for options granted through March 31, 2005 was originally determined by our board of directors, with input from management. We did not obtain contemporaneous valuations by an unrelated valuation specialist in connection with these grants. Instead, we relied on our board of directors, the members of which we believe have extensive experience in the medical device market and are accredited venture capital investors, to determine a reasonable estimate of the then-current fair value of our common stock. Since there was no public market for our shares, our board of directors exercised judgment in determining the estimated fair value of our common stock on the date of grant based on several factors, including transactions in our preferred and common stock, the rights and benefits that preferred stock holders are entitled to that holders of our common stock are not, key milestones achieved in our business including forecasted revenues and cash flows, product development and market acceptance, our financial condition, equity market conditions, and the likelihood of continuing as a going

concern. Based on these factors, we granted options for the period from January 1, 2004 through March 31, 2005 at exercise prices ranging from \$0.33 to \$1.65.

Subsequently, we reassessed the valuations of our common stock relating to options granted beginning with the 2004 fiscal year. As part of this reassessment, our board of directors obtained retrospective valuations prepared by management, which management believes follows substantially the same methodology used by valuation specialists as outlined in the AICPA's *Practice Aid Valuation of Privately-Held-Company Equity Securities Issues as Compensation*. Based on these retrospective valuations, the fair value of the common stock underlying options granted in the period from January 1, 2004 through March 31, 2005 was determined to be from \$0.83 to \$5.06. In addition to the factors discussed above which our board of directors considered in determining the estimated fair value of our common stock, they also considered the market release of a new IVUS catheter in early 2004, the sale of our Series C preferred stock to accredited investors in early 2005, the expansion of our Japanese distribution channel in early 2005 and the potential impact that liquidity events would have on us such as an initial public offering, a merger or sale with another company, or the forced liquidation of our company.

The procedures performed as part of the retrospective valuations for determining the fair value of our common stock were based on a probability-weighted combination of the market multiple approach and income approach to estimate the aggregate equity value at specific stock option grant dates.

The market multiple approach was based on revenues, earnings before interest, taxes, depreciation and amortization, or EBITDA, and net income considered to be representative of our future performance, and multiplying these figures by a range of appropriate risk-adjusted multiples. The market multiples were obtained through the market comparison method, where companies having their stock traded in the public market were used as a basis for choosing reasonable market multiples.

The income approach involves applying appropriate discount rates to estimated debt-free cash flows that are based on forecasts of our revenue and costs. The projections used for each valuation date were based on the expected outlook on our operating performance through the forecast periods. The assumptions underlying the estimates were consistent with our board of directors' approved business plan. The future debt-free cash flows were determined by subtracting from EBITDA taxes and future capital spending and adjusting for future changes in net working capital. The interim debt-free cash flows and resulting terminal value were then discounted at a rate based on the weighted-average cost of capital of comparable companies, as adjusted for our specific risk profile. There is inherent uncertainty in these estimates. If different discount rates had been used, the valuations would have been different.

After estimating our average value based on the market multiple and income approaches, we then utilized a probability-weighted expected return method. Under the probability-weighted expected return method, the value of our common stock was estimated based upon an analysis of values assuming various outcomes, such as an initial public offering, merger or sale, forced liquidation, and remaining private, and the estimated probability of each outcome assuming that all preferred stock is converted into common stock.

From April 2005 until our initial public offering in June 2006, our board of directors obtained contemporaneous valuations prepared by management which follow the same procedures as those used in the retrospective valuations described above. In addition to the factors discussed above, our board of directors considered specific business milestones including the introduction of VH IVUS functionality for our IVUS IVG consoles in May 2005, the sale of common stock to two new independent members of the board of directors in the fourth quarter of 2005 and the initial release of our new s5 console in late 2005. In addition, we considered the events occurring late in 2005 concerning our potential initial public offering, including our meetings with potential investment bankers.

For financial reporting purposes for the period from January 1, 2004 through December 31, 2005, for options granted to employees we recorded deferred stock-based compensation under APB No. 25 representing the difference between the estimated fair value of common stock and the option exercise price. Beginning January 1, 2006, with the adoption of SFAS No. 123(R), we recorded stock-based compensation based upon estimated fair values. The following table shows information concerning all options granted during the period January 1, 2005 through December 31, 2007:

Grant Date	Number of Options Granted	Option rcise Price	Fair Value of Common Stock on Grant Date (1)	Intrinsic Value Per Share	
2005 Grants					
January	153,456	\$ 0.83	\$ 5.06	\$	4.23
January	117,568	1.65	5.06		3.41
April	195,455	5.78	5.78		_
June	90,455	5.78	5.78		_
July	908,636	6.49	6.49		_
October	270,273	8.36	8.36		_
Total 2005 grants	1,735,843				
2006 Grants					
February	145,406	\$ 10.56	\$10.56	\$	_
May	91,339	10.56	10.56		_
July	66,500	8.50	8.50		_
November	61,000	18.10	18.10		
Total 2006 grants	364,245				
2007 Grants .					
January	1,071,456	\$ 19.15	\$19.15	\$	_
April	83,000	18.36	18.36		_
June	76,000	21.07	21.07		_
July	481,833	20.22	20.22		_
October	131,000	17.27	17.27		_
December	124,666	13.52	13.52		_
Total 2007 grants	1,967,955				

<sup>(1)</sup> The estimated fair values for January 1, 2005 have been determined based upon retrospective valuations prepared by management and the estimated fair values shown for the period April 1, 2005 through the date of our initial public offering are based upon contemporaneous valuations prepared by management.

In connection with the grant of stock options to employees and directors under APB No. 25, we recorded an aggregate of \$4.3 million in deferred stock-based compensation, with respect to stock options granted through December 31, 2005. In total, we amortized \$1.5 million of deferred stock compensation into expense through December 31, 2005. As of December 31, 2005, our deferred stock compensation under APB No. 25 was \$2.9 million. As required under SFAS 123(R), the \$2.9 million in deferred stock compensation was reversed in January 2006. At December 31, 2006, we therefore had no remaining deferred stock compensation.

Prior to our initial public offering in June 2006, the determination of the fair value of our common stock involved significant judgments, assumptions, estimates and complexities that impacted the amount of deferred stock-based compensation recorded under APB No. 25 and the resulting amortization in future periods. Under SFAS No. 123(R), we have used the Black-Scholes valuation model to estimate fair value of our stock-based awards which requires various judgmental assumptions including estimating stock price volatility, expected life and forfeiture rates. If we

had made different assumptions, the amount of our deferred stock-based compensation, stock-based compensation expense, gross margin, net loss and net loss per share amounts could have been significantly different. We believe that we have used reasonable methodologies, approaches and assumptions to determine the fair value of our common stock and that deferred stock-based compensation and related amortization were recorded properly for accounting purposes. If any of the assumptions used change significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period.

Under SFAS No. 123 and SFAS 123(R), the fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model utilizing the following weighted-average assumptions:

	Years Ended December 31		
	2007	2006	2005
Risk-free interest rate	4.67%	4.76%	3.9%
Expected life (years)	4.52	4.56	5.00
Estimated volatility factor	51.7%	57.4%	75.0%
Expected dividends	None	None	None

The risk-free interest rate for periods within the contractual life of the option is based on the implied yield available on U.S. Treasury constant rate securities with the same or substantially equivalent remaining terms at the time of grant.

For options granted prior to January 1, 2006, and valued in accordance with SFAS No. 123, the expected life of our stock options was based upon the historical experience of similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and expectations of future employee behavior. We recognized option forfeitures as they occurred as allowed by SFAS No. 123. Estimated volatility was calculated using the implied volatility of the common stock of comparable medical device companies.

For options granted after January 1, 2006, and valued in accordance with SFAS No. 123(R), we adopted a temporary "shortcut approach" as permitted by SAB No. 107 to develop an expected life of an employee stock option. Under this approach, the expected life is presumed to be the mid-point between the vesting date and the contractual end of the option term. We estimate forfeitures and only recognize expense for those shares expected to vest. Our estimated forfeiture rates in the years ended December 31, 2007 and 2006 are based on our historical forfeiture experience. Estimated volatility under SFAS No. 123(R) is calculated using the trading history of the common stock of comparable medical device companies.

In the year ended December 31, 2005, the compensation committee of our Board of Directors approved the acceleration of vesting of certain non-employee stock options representing options to purchase 84,545 shares of our common stock. In connection with the acceleration of the vesting of these options, we recorded charges totaling \$412,000 in the year ended December 31, 2005.

As of December 31, 2007, we had approximately \$18 million of unrecognized compensation cost remaining to be amortized over a weighted-average term of 3.0 years.

**Income Taxes.** We account for income taxes in accordance with SFAS No. 109, Accounting for Income Taxes. Our deferred tax assets are determined by multiplying the differences between the financial reporting and tax reporting bases for assets and liabilities by the enacted tax rates expected to be in effect when such differences are expected to be recovered or settled.

The realization of our deferred tax assets, which had a gross carrying value of \$29.3 million at December 31, 2007, is dependent upon our ability to generate sufficient future taxable income. We have established a full valuation allowance against our deferred tax assets to reflect the uncertainty of realizing the deferred tax benefits, given our historical losses. A valuation allowance is required when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence needs to be considered, including our past and future performance, the market environment in which we operate, the utilization of tax attributes in the past, and the length of carryforward periods and evaluation of potential tax planning strategies. We expect to continue to maintain a full valuation allowance until an appropriate level of profitability is sustained or we

are able to develop tax strategies that would enable us to conclude that it is more likely than not that a portion of our deferred tax assets would be realizable.

#### **Recent Accounting Pronouncements**

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" (SFAS 157), which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 will be effective for fiscal years beginning after November 15, 2007 and we will adopt SFAS 157 beginning January 1, 2008. We are currently assessing the potential impact the adoption of SFAS 157 will have on our consolidated results of operations and financial position.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115" (SFAS 159). SFAS 159 expands the use of fair value accounting but does not affect existing standards which require assets or liabilities to be carried at fair value. Under SFAS 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred, e.g., debt issue costs. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS 159, changes in fair value are recognized in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We will adopt SFAS 159 for our fiscal year beginning January 1, 2008. We are currently determining whether fair value accounting is appropriate for any of the eligible items and we cannot estimate the impact, if any, the adoption of SFAS 159 will have on our consolidated results of operations and financial position.

In December 2007, the FASB issued SFAS No. 141 (Revised 2007), Business Combinations, or SFAS No. 141(R). SFAS No. 141(R) will change the accounting for business combinations. Under SFAS No. 141(R), an acquiring entity will be required to recognize all the assets acquired and liabilities assumed in a transaction at the acquisition-date fair value with limited exceptions. SFAS No. 141(R) will change the accounting treatment and disclosure for certain specific items in a business combination. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Accordingly, any business combinations we engage in will be recorded and disclosed following existing GAAP until January 1, 2009. We expect SFAS No. 141(R) will have an impact on accounting for business combinations once adopted but the effect is dependent upon acquisitions at that time. We are still assessing the impact of this pronouncement.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements—An Amendment of ARB No. 51, or SFAS No. 160. SFAS No. 160 establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS No. 160 is effective for fiscal years beginning on or after December 15, 2008. We have not completed our evaluation of the potential impact, if any, of the adoption of SFAS No. 160 on our consolidated financial position, results of operations and cash flows.

#### Inflation

We believe that inflation has not had a material impact on our historical results of operations; however, there can be no assurance that our business will not be affected by inflation in the future.

### Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Market risk represents the risk of changes in the value of market risk sensitive instruments caused by fluctuations in interest rates, foreign exchange rates and commodity prices. Changes in these factors could cause fluctuations in our results of operations and cash flows. In the ordinary course of business, we are exposed to interest rate and foreign exchange risk. Fluctuations in interest rates and the rate of exchange between the U.S. dollar and foreign currencies, primarily the Euro, could adversely affect our financial results.

#### Interest Rate Risk

Our exposure to interest rate risk at December 31, 2007 is related to the investment of our excess cash into highly liquid financial investments. As of December 31, 2007, we held \$189.1 million in cash, cash equivalents and short-term available-for-sale investments consisting of highly liquid financial investments with original maturities of one year or less. Based upon our balance of cash and cash equivalents and short-term available-for-sale investments, a decrease in interest rates of 100 basis points would cause a corresponding decrease in our annual interest income of approximately \$1.9 million for these investments. Due to the nature of our highly liquid cash equivalents and short-term available-for-sale investments, a change in interest rates would not materially change the fair market value of our cash equivalents and short-term available-for-sale investments.

The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments. Due to the short-term nature of our investments, we have assessed that there is no material exposure to interest rate risk arising from them.

#### Foreign Currency Exchange Risk

We are exposed to foreign currency risk related to our European operations, including Euro denominated intercompany receivables. Because our intercompany receivables are accounted for in Euros, any appreciation or devaluation of the Euro will result in a gain or loss to the consolidated statements of operations.

### Item 8. Financial Statements and Supplementary Data

### **VOLCANO CORPORATION**

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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Volcano Corporation

We have audited Volcano Corporation's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Volcano Corporation's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Volcano Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Volcano Corporation as of December 31, 2007 and 2006, and the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2007, and our report dated March 13, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Sacramento, California March 13, 2008

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Volcano Corporation

We have audited the accompanying consolidated balance sheets of Volcano Corporation as of December 31, 2007 and 2006, and the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Volcano Corporation at December 31, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the consolidated financial statements, in 2006 the Company adopted Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, and in 2007 the Company adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Volcano Corporation's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 13, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Sacramento, California March 13, 2008

### **VOLCANO CORPORATION**

# CONSOLIDATED BALANCE SHEETS (in thousands, except per share data)

		December 31,		
		2007		2006
Assets				
Current assets:				
Cash and cash equivalents	\$	122,913	\$	77,738
Short-term available-for-sale investments		66,205		17,787
Accounts receivable, net		27,976		21,575
Inventories		21,243		13,423
Prepaid expenses and other current assets		3,997	_	2,208
Total current assets		242,334		132,731
Restricted cash		365		352
Property and equipment, net		13,692		9,333
Intangible assets, net		9,385		11,946
Other non-current assets		798	_	363
	\$	266,574	\$	154,725
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	\$	11,077	\$	8,209
Accrued compensation		9,083		5,993
Accrued expenses and other current liabilities		6,600		5,292
Deferred revenues		5,360		2,675
Current maturities of long-term debt		120		1,654
Total current liabilities		32,240		23,823
Long-term debt		78		66
Deferred license fee from a related party		1,125		1,375
Other		194		279
Total liabilities	•	33,637		25,543
Commitments and contingencies (Note 8)				
Stockholders' equity:				
Common stock, par value of \$0.001; 250,000 shares authorized at December 31, 2007 and 2006; 46,957 and 37,720 shares issued and				
outstanding at December 31, 2007 and 2006, respectively		47		38
Additional paid-in capital		324,746		193,468
Accumulated other comprehensive loss		(1,258)		(302)
Accumulated deficit		(90,598)		(64,022)
Total stockholders' equity		232,937		129,182
	<u>\$</u>	266,574	<u>\$</u>	154,725

See notes to consolidated financial statements.

### **VOLCANO CORPORATION**

# CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share data)

	Years Ended December 31,					
		2007		2006		2005
Revenues	\$	130,614	\$	103,048	\$	91,900
Cost of revenues		51,559		41,715		47,843
Gross profit		79,055		61,333		44,057
Operating expenses:						
Selling, general and administrative		62,631		47,614		35,365
Research and development		20,315		16,923		15,119
In-process research and development		26,188		_		_
Amortization of intangibles		3,067		3,117		3,052
Total operating expenses		112,201	_	67,654		53,536
Operating loss		(33,146)		(6,321)		(9,479)
Interest income		5,841		958		458
Interest expense		(199)		(4,013)		(5,311)
Exchange rate gain (loss)		1,452		1,053		(859)
Other, net			_	18		
Loss before provision for income taxes		(26,052)		(8,305)		(15,191)
Provision for income taxes		524		298		70
Net loss	\$	(26,576)	<u>\$</u>	(8,603)	\$	(15,261)
Net loss per share—basic and diluted	\$	(0.66)	\$	(0.41)	\$	(2.28)
Weighted—average shares outstanding—basic and diluted		40,024		21,113	_	6,693

See notes to consolidated financial statements.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) VOLCANO CORPORATION

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	Designated Series A Convertible Preferred Stock	Designated Series B Convertible Preferred Stock	Designated Series C Convertible Preferred Stock	k Common Stock		Additional	Deferred	•	Accumulated Other	Total Stockholders'
	Shares Amount	1	Shares Amount	1 1	mount	- 1	Stock Compensation	Deficit	Income (loss)	(Deficit)
Balance at December 31, 2004 Issuance of common stock under stock option plans Deferred stock compression	2,304 \$ 2,304	14,949 \$ 45,392	, , ,	- 3,617 181	<b>2</b> 1	6.182 88 1,239	\$(3,006)	\$(40,158)	8	\$(36,976) 88 —
reversal or inanimizate activities suck compensation relating to use toursaison employee stock options.  Amortization of deferred stock compensation net of adjustment for forfeitures of unvested options.  Non-employee stock compensation expense.  Non-employee stock compensation expense.  Sale of common stock is exchange for consulting services.	٠		2,662 15,364	4 27 13	1.1	(255) 736 (258) 601	255 1,102			1,102 736 736 (258) 601
Comprehensive income (toss) Net loss Foreign currency translation adjustments Total comprehensive income (toss)								(15,261)	390	(15.261)
	2,304 2,304	14,949 45,392	2,662 15,364	3,883	4	8,443	(2,888)	(55,419)	392	(49,468)
Issuance of centures stock confirmation upon adoption of strategies of centures stock under stock option plans  Employee stock-that compensation cost.				466	1	2.91 2.913 2.913				194 2,913 434
offering	(2,304) (2,304)	12,115 (2,304) (2,304) (14,949) (45,392) (2,662) (15,364) 18,123 3,133	(2,662) (15,36	12,115 4) 18,123 3,133	3.5	121,334 63,041 (3)				63,060
Comprehensive loss Net loss Net loss on investments Unrealized net loss on investments								(8,603)	(693)	· (8,603) · (693) .
Total comprehensive loss				•				!		(9,297)
Balance at December 31, 2006  Issuance of common stock under stock option plans Employee stock-based compensation cost.  Non-employee stock-based compensation cost.  Common stock issued in councection with public offerings.	1	<b>l</b>	1	- 37,720 1,152 8,050	æ – »	193,468 1,695 6,454 341 122,788	ļ	(64,022)	(302)	129,182 1,696 6,454 341 122,796
Exercise of warrants				35	I					I
Net loss Foreign currenty translation adjustments Unrealized net gain on investments That commercements								(26.576)	(1,012)	(26,576) (1,012) 56 (27,532)
Balance at December 31, 2007	- \$ -	- 8 -	. \$ -	- 46,957	547	\$324,746	- 5	\$(90,598)	\$(1,258)	\$232,937

See notes to consolidated financial statements.

# VOLCANO CORPORATION CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands)

		Years	End	ed Decemb	er 3	1,
		2007		2006	_	2005
Operating activities						
Net loss	\$	(26,576)	\$	(8,603)	\$	(15,261)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:						
In-process research and development expense		26,188		_		
Depreciation and amortization		7,902		8,480		7,100
Amortization and write-off of debt discount and deferred financing fees		102		1,781		808
Accretion of investment discount, net		(1,195)		_		
Impairment of long-lived assets		_				360
Interest capitalized as debt principal		_		1,973		3,774
Non-cash stock compensation expense		6,795		3,195		1,948
Loss (gain) on foreign exchange		(1,452)		(1,052)		859
Loss on disposal of long-lived assets		222		_		34
Changes in operating assets and liabilities, net of acquisitions:		(5.046)		(E 070)		// / 10°
Accounts receivable		(5,846)		(5,078)		(4,110)
Inventories		(7,659)		(2,992)		(2,684)
Prepaid expenses and other assets		(1,942)		(399)		(697)
Accounts payable		2,217		(2,682)		6,281
Accrued compensation		2,980		1,505		1,223
Accrued expenses and other liabilities.		110		283		2,441
Deferred revenues.		2,390		465		804
Deferred license fee from a related party	_			(250)		(250)
Net cash provided by (used in) operating activities		4,236		(3,374)	_	2,630
Investing activities						
Purchase of short-term available-for-sale securities		(105,823)		(17,853)		
Sale or maturity of short-term available-for-sale securities		58,655		_		_
Capital expenditures		(9,101)		(4,990)		(5,585)
Cash paid for acquisitions		(25,158)				_
Cash paid for other intangibles		(233)		(373)		(434)
Proceeds from sale of long-lived assets		45		50		
Net cash used in investing activities		(81,615)		(23,166)		(6,019)
Financing activities						
Proceeds from underwritten public stock offerings, net		122,796		121,346		
Proceeds from issuance of long-term debt		· · · —		·		500
Repayment of long-term debt		(1,774)		(32,384)		(2,963)
Proceeds from issuance of short-term debt				750		
Repayment of short-term debt		_		(750)		(5,897)
Proceeds from issuance of convertible preferred stock, net of issuance costs				· —		15,106
Proceeds from sale of common stock		<del></del>		_		601
Proceeds from exercise of common stock options		1,687		178		63
Increase in restricted cash		· —		(34)		(82)
		122 700	_	<del></del>	_	<del></del>
Net cash provided by financing activities		122,709		89,106		7,328
Effect of exchange rate changes on cash and cash equivalents		(155)	_	(47)		(158)
Net increase in cash and cash equivalents		45,175		62,519		3,781
Cash and cash equivalents, beginning of year	_	77,738		15,219	_	11,438
Cash and cash equivalents, end of year	\$	122,913	\$	77,738	\$	15,219
Supplemental disclosures						
Interest capitalized as debt principal		_	\$	1,973	\$	_
Cash paid for interest		118	\$	259	\$	827
Cash paid for income taxes	\$	510	\$	71	\$	39
Non-cash investing and financing activities						
Preferred stock converted into common stock upon initial public offering		_	\$	63,060		_
See notes to consolidated financial statements.						

#### **VOLCANO CORPORATION**

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Summary of Significant Accounting Policies

#### Basis of Presentation and Nature of Operations

Volcano Corporation (formerly Volcano Therapeutics, Inc.) was incorporated under the laws of the State of Delaware on January 12, 2000. Our consolidated financial statements include the accounts of the parent company and its wholly-owned subsidiaries, Volcano Europe SA/NV, formerly Volcano Therapeutics Europe (Volcano Europe) and Volcano Japan Co. Ltd., formerly Volcano Therapeutics Japan Co. Ltd. (Volcano Japan). Volcano Europe was incorporated in 2003 and Volcano Japan was incorporated in 2004. We engage in the manufacture, sale, discovery, development and commercialization of products for the diagnosis of atherosclerosis in the coronary arteries and peripheral vascular system. All significant intercompany balances and transactions have been eliminated in consolidation.

In July 2003, we purchased substantially all of the assets and assumed certain liabilities associated with the Intravascular Ultrasound (IVUS) and Functional Measurement (FM) product lines of Jomed, Inc. and certain other affiliates and subsidiaries of Jomed, NV (the Jomed Acquisition).

#### Reverse Stock Split

On May 22, 2006, our Board of Directors and stockholders approved a 1-for-1.1 reverse split of our common stock and, on May 24, 2006, we filed a Certificate of Amendment to our Restated Certificate of Incorporation effecting the reverse split. All common share and per share amounts retroactively reflect the reverse stock split. Except as otherwise noted, references to preferred stock do not reflect the reverse stock split, as the conversion price for each series of preferred stock and the number of shares of common stock into which each share of preferred stock is convertible were adjusted, in accordance with the terms and conditions of such series of preferred stock, upon the filing of the Certificate of Amendment to reflect the reverse stock split.

#### Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Estimates are used for, but not limited to, the accounting for doubtful accounts, inventory reserves, depreciation and amortization, sales returns, warranty costs, certain accruals, long-lived asset impairment calculations and contingencies. Actual results could differ materially from the estimates and assumptions we use in the preparation of our consolidated financial statements.

### Foreign Currency Translation

The Euro is the functional currency of our subsidiary, Volcano Europe, as it is the primary currency within the economic environment in which it operates. Assets and liabilities of Volcano Europe's operations are translated into U.S. dollars at period-end exchange rates, and revenues and expenses are translated into U.S. dollars at average exchange rates in effect during each reporting period. Adjustments resulting from the translation are reported in other comprehensive loss.

Exchange rate fluctuations resulting from the translation of the inter-company balances between Volcano Corporation U.S. and Volcano Europe and other non-U.S. dollar denominated liabilities into U.S. dollars are recorded as foreign currency transaction gains or losses and are included in exchange rate gain (loss) in the consolidated statement of operations.

The U.S. dollar is the functional currency of our subsidiary, Volcano Japan, as it is the primary currency within the economic environment in which it operates. Yen-based assets and liabilities of our Japanese operations are translated into U.S. dollars at period-end exchange rates, and Yen-based expenses are translated into U.S. dollars at

average exchange rates in effect during each reporting period. Adjustments resulting from the translation are recorded as foreign currency transaction gains or losses and are included in exchange rate gain (loss) in the consolidated statement of operations.

#### Financial Instruments

Our financial instruments include cash and cash equivalents, short-term available-for-sale investments, accounts receivable, accounts payable, certain other accrued liabilities and debt. The carrying amounts of cash and cash equivalents, short-term available-for-sale investments, accounts receivable, accounts payable and other accrued liabilities approximate their fair values due to the short-term nature of those instruments. Active markets for our other debt instruments, which consist of privately-issued notes payable and term loans, do not exist and there are no quoted market prices for these liabilities. Accordingly, it is not practicable for us to estimate the fair values of such financial instruments because of the limited information available.

#### Cash and Cash Equivalents

All highly liquid investments with a maturity of three months or less on the date of purchase are considered to be cash equivalents.

#### Short-term Investments

Our short-term available-for-sale investments consist of highly liquid financial investments with original maturities of greater than three months, but less than one year. All short-term investments are classified as available for sale and are recorded at market value using the specific identification method. Unrealized gains and losses are reflected in Other Comprehensive Loss.

#### Restricted Cash

At December 31, 2007 and 2006, we had restricted cash totaling \$365,000 and \$352,000, respectively. Restricted cash of \$231,000 at December 31, 2007 and 2006 is in the form of collateral to a letter of credit issued to one of our principal landlords as a security deposit on a lease that expires in 2009. An additional \$134,000 and \$121,000 at December 31, 2007 and 2006, respectively, is cash in bank, restricted as to withdrawal and serves as a security deposit for another leased facility pursuant to a lease that expires in 2013. The letter of credit is in effect and the cash in bank will remain restricted as to withdrawal until such time as new lease agreements are executed.

# Concentration of Credit Risk

Financial instruments which subject us to potential credit risk consist of our cash and cash equivalents, short-term investments and accounts receivable. We have established guidelines to limit our exposure to credit expense by placing investments with high credit quality financial institutions, diversifying our investment portfolio and placing investments with maturities that maintain safety and liquidity. We place our cash and cash equivalents with high credit quality financial institutions. Deposits with these financial institutions may exceed the amount of insurance provided; however, these deposits typically are redeemable upon demand and, therefore, we believe the financial risks associated with these financial instruments are minimal.

We perform ongoing credit evaluations of our customers, and generally we do not require collateral on our accounts receivable. We estimate the need for allowances for potential credit losses based on historical collection activity and the facts and circumstances relevant to specific customers and we record a provision for uncollectible accounts when collection is uncertain. To date, we have not experienced significant credit related losses.

Fukuda Denshi Co., Ltd, a distributor in Japan, accounted for 14%, and 35% of our revenues for the years ended December 31, 2006 and 2005, respectively, and 14% of our trade receivables at December 31, 2006. Goodman Company, Ltd., a distributor in Japan, accounted for 18% and 15% of our revenues for the years ended December 31, 2007 and 2006, respectively, and 21% and 14% of our trade receivables at December 31, 2007 and 2006, respectively. No other single customer accounted for more than 10% of our revenues for any period presented and at December 31, 2007 and 2006, no other single customer accounted for more than 10% of our trade receivables.

We purchase integrated circuits and other key components for use in our products. For certain components, which are currently single sourced, there are relatively few sources of supply. Although we believe that other suppliers could provide similar components on comparable terms, establishment of additional or replacement suppliers cannot be accomplished quickly. Any significant supply interruption could have a material adverse effect on our business, financial condition and results of operations.

#### Inventories

Inventories are valued at the lower of cost (first-in, first-out basis) or market value (net realizable value or replacement cost).

# Property and Equipment

Property and equipment is stated at cost, net of accumulated depreciation and amortization. Equipment and capitalized software are depreciated over the estimated useful lives of the assets (generally three to five years). Leasehold improvements are amortized over the lesser of the lease term or the estimated useful lives of the improvements, which is between three and ten years. The straight-line method is used for depreciation and amortization. Significant improvements which substantially extend the useful lives of assets are capitalized. Expenditures for maintenance and repairs are charged to expense as incurred.

Property and equipment includes certain medical diagnostic equipment that is located at customer premises. This equipment is placed at our discretion with certain customers, such as key opinion leaders and other strategic customers who agree to use the equipment and purchase specified quantities of our single-procedure disposable products. We retain the ownership of the equipment and have the right to remove the equipment if it is not being utilized according to expectations. Depreciation expense relating to this equipment of \$1.8 million, \$1.8 million and \$1.4 million is recorded in cost of revenues during the years ended December 31, 2007, 2006 and 2005, respectively. The net book value of this equipment was \$4.8 million and \$2.1 million at December 31, 2007 and December 31, 2006, respectively. Also included in medical diagnostic equipment is property and equipment used for demonstration and evaluation purposes. Depreciation expense for equipment used for demonstration and evaluation purposes is recorded in selling, general and administrative expenses. Depreciation expense relating to this equipment of \$793,000, \$515,000 and \$335,000 is recorded in selling, general and administrative expenses during the years ended December 31, 2007, 2006 and 2005, respectively. The net book value of this equipment was \$2.9 million and \$1.0 million at December 31, 2007 and December 31, 2006, respectively. Medical diagnostic equipment is recorded at our cost to acquire or manufacture the equipment and is depreciated over the estimated useful life (generally three to five years).

Assets held under capital leases are recorded at the net present value of the minimum lease payments of the leased asset at the inception of the lease. Amortization expense is computed using the straight-line method over the shorter of the estimated useful lives of the assets or the period of the related lease.

# Intangible Assets

Intangible assets, consisting of acquired technology, licenses, patents and trademarks, and customer relationships, are amortized using the straight-line method over their estimated useful lives ranging from three to ten years.

# Impairment or Disposal of Long-Lived Assets

Impairment of long-lived assets is recognized when events or circumstances indicate that the carrying amount of the asset, or related groups of assets, may not be recoverable. Under Statement of Financial Accounting Standard (SFAS) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS No. 144), a long-lived asset is initially measured at the lower of its carrying amount or fair value. An impairment loss is recognized when estimated future cash flows, on an undiscounted basis, expected to result from the use of the asset, including its disposition, are less than the carrying value of the asset. The impairment loss is then calculated by comparing the carrying value of the asset with its fair value, which is usually estimated using discounted cash flows expected to be generated from the use of the assets.

#### **Product Warranty Costs**

We offer a one-year warranty for parts and labor on our products commencing upon the transfer of title and risk of loss to the customer. We accrue the estimated cost of product warranties at the time revenue is recognized based on historical results. The warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from these estimates, revisions to the estimated warranty liability would be required. We periodically assess the adequacy of our recorded warranty liabilities and adjust the amounts as necessary.

Accrued warranty liability is included in accrued expenses and other current liabilities in the consolidated balance sheets. The change in the accrued warranty liability for the years ended December 31, 2007, 2006 and 2005 is summarized in the following table (in thousands):

	Years Ended December 31,					
		2007	2006			2005
Balance at beginning of year	\$	706	\$	359	\$	203
Warranties issued during the year		2,342		1,028		611
Settlements during the year		(1,919)	_	(681)		(455)
Balance at end of year	\$	1,129	\$	706	\$	359

# Derivative Financial Instruments

In accordance with SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities (SFAS No. 133), we performed a review of our contracts for potential derivative financial instruments. Embedded derivative financial instruments are present within our debt agreements (see "Debt and Credit Facilities" note to our consolidated financial statements).

#### Stock-Based Compensation

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment, (SFAS No. 123(R)) which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors based on estimated fair values. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 (SAB No. 107) relating to SFAS No. 123(R) and we have applied the provisions of SAB No. 107 in our adoption of SFAS No. 123(R). Prior to January 1, 2006, we accounted for share-based payments using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25), and related Interpretations, as permitted by SFAS No. 123, Accounting for Stock-Based Compensation (SFAS No. 123). In accordance with APB No. 25, stock-based compensation expense had been recognized only when the fair market value of our stock options granted to employees and directors was greater than the exercise price of the underlying stock at the date of grant.

We adopted SFAS No. 123(R) using the modified-prospective-transition method. Under that transition method, stock-based compensation cost recognized in the year ended December 31, 2006 includes stock-based compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and stock-based compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). SFAS No. 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods using the straight-line method. SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In our pro forma information required under SFAS No. 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred. In accordance with the modified-prospective transition method, prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123(R). See "Stockholders' Equity" note to our consolidated financial statements.

Prior to January 1, 2006, had compensation expense for our stock option plans been determined based upon the fair value at the grant date for awards under the plans using market-based option valuation models, net loss would have been as follows (in thousands, except per share data):

		nber 31, 2005
Net loss as reported	\$	(15,261)
Add: Total stock-based employee compensation determined under APB 25 and included in reported net loss		1,102
Deduct: Total stock-based employee compensation determined under fair value based		
method		(1,800)
Pro forma net loss	<u>\$</u>	(15,959)
Basic and diluted net loss per share:		
As reported	<u>\$</u>	(2.28)
Pro forma	\$	(2.38)

Option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options and because changes in the input assumptions can materially affect their fair value estimate, it is our opinion that the existing models do not necessarily provide a reliable single measure of the fair value of the employee stock options. For purposes of pro forma disclosures, the estimated fair value of options is amortized to expense over the vesting period of equity awards (generally four years), using the straight-line method.

Under SFAS No. 123, the fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model utilizing the following weighted-average assumptions:

# **Stock Option Plan**

	Years Ended December 3		
	2007	2006	2005
Risk-free interest rate	4.67%	4.76%	3.9%
Expected life (years)	4.52	4.56	5.00
Estimated volatility factor	51.7%	57.4%	75.0%
Expected dividends	None	None	None

The first offering period under the Employee Stock Purchase Plan commenced in September 2007. Under SFAS No. 123, the fair value of each purchase option under the Employee Stock Purchase Plan is estimated at the beginning of this purchase period using the Black-Scholes option-pricing model utilizing the following assumptions:

# **Employee Stock Purchase Plan**

	Years End	iber 31,	
	2007	2006	2005
Risk-free interest rate			
Expected life (years)	0.49		_
Estimated volatility factor	49.0%		
Expected dividends	None	_	_

Risk-Free Interest Rate—We base the risk-free interest rate used in the Black-Scholes valuation method on the implied yield currently available on U.S. Treasury constant maturity securities with the same or substantially equivalent remaining term.

Expected Life—Our expected life represents the period that our stock-based awards are expected to be outstanding. With the adoption of SFAS No. 123(R) on January 1, 2006, as permitted by SAB No. 107, we adopted a temporary "shortcut approach" to developing the estimate of the expected term of an employee stock option. Under this approach, the expected life is presumed to be the mid-point between the vesting date and the contractual end of the option grant. Prior to the adoption of SFAS No. 123(R), expected life of our stock options was determined based on historical experience of similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and expectations of future employee behavior as influenced by changes to the terms of its share-based awards.

Estimated Volatility Factor—We use the calculated volatility based upon the trading history and implied volatility of our common stock and the common stock of comparable medical device companies in determining an estimated volatility factor when using the Black-Scholes option-pricing formula to determine the fair value of options granted.

Expected Dividends—We have not declared dividends nor do we expect to for the foreseeable future. Therefore, we use a zero value for the expected dividend value factor when using the Black-Scholes option-pricing formula to determine the fair value of options granted.

Estimated Forfeitures—When estimating forfeitures, we consider our historical voluntary and involuntary termination behavior as well as analysis of actual option forfeitures.

# Option and Warrant Grants to Non-employees

Option and warrant grants to non-employees are valued using the fair value based method prescribed by SFAS No. 123 and Emerging Issues Task Force (EITF) Issue No. 96-18, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services.

#### Comprehensive Loss

Comprehensive loss represents the net loss for the period plus the results of certain changes to stockholders' equity (deficit) that are not reflected in the consolidated statements of operations. Our comprehensive loss consists of net losses, unrealized net gains and losses on short-term investments and foreign currency translation adjustments.

# Revenue Recognition

In December 2003, the Securities and Exchange Commission (the SEC) issued Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition (SAB No. 104), which superseded SAB No. 101, Revenue Recognition (SAB No. 101). We recognize revenues in accordance with SAB No. 104 when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectibility is reasonably assured. Revenue from the sale of our products is generally recognized when title and risk of loss transfer upon shipment to the customer (generally FOB shipping point).

We occasionally enter into agreements requiring cash payments to partners who are also customers. We apply the provisions of EITF 01-09, Accounting for Consideration Given by a Vendor to a Customer, to account for cash payments made under these agreements. During the year ended December 31, 2007, we made payments to customers of approximately \$1.0 million, which have been recorded as a reduction in revenues in accordance with this EITF.

Installation and training are generally not required elements of our sales transactions as most of our products do not require installation and training. In instances where installation and training are required elements of the sales transaction, revenue is recognized upon completion of the installation and training.

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Our revenue arrangements can include multiple elements or deliverables. These elements can consist of consoles, options for the console, single-procedure disposable products and a service and maintenance agreement. The sale of these products and services are often contemplated in a single arrangement with delivery of the elements sometimes occurring in different periods. If an arrangement includes multiple elements, we apply the provisions of Emerging Issues Task Force, or EITF, Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. The principles and

guidance outlined in EITF No. 00-21 provide a framework to (a) determine whether an arrangement involving multiple deliverables contains more than one unit of accounting, and (b) determine how the arrangement consideration should be measured and allocated to the separate units of accounting in the arrangement. In accordance with EITF No. 00-21, we use the residual method to allocate the arrangement consideration when we have not established objective and reliable evidence of the fair value of delivered items. The delivered items represent individual units of accounting because they have value to the customer on a stand-alone basis, objective and reliable evidence of fair value exists for the undelivered items, and arrangements do not contain a general right of return relative to the delivered items. Under the residual method, the amount of consideration allocated to the delivered items equals the total arrangement consideration less the aggregate fair value of the undelivered items.

Assuming all other criteria for revenue recognition have been met, we recognize revenue for delivered items when title and risk of loss transfer upon shipment to the customer and installation, if applicable, has been completed. Revenue for undelivered items, which include service and maintenance activities, is recognized ratably over the service period, which is generally one year.

All costs associated with the provision of service are recognized in cost of revenues as incurred. Amounts billed in excess of revenue recognized are included as deferred revenue in the consolidated balance sheets.

We sell our products through direct sales representatives in the United States and a combination of direct sales representatives and independent distributors in international markets. Sales to distributors are recorded when title and risk of loss transfer upon shipment (generally FOB shipping point). No direct sales customers or distributors have price protection and only one distributor has limited return rights in the event of termination of the agreement with that distributor. We periodically make evaluations regarding the estimated amount of returns that could be made under this right of return provision in accordance with SFAS No. 48, Revenue Recognition When Right of Return Exists. Estimated returns, which are based on historical results, are recorded as allowances for sales returns and as a reduction in revenues.

# Shipping and Handling Costs

Shipping and handling costs billed to customers are included in revenues. Shipping and handling costs we incur associated with shipping products to our customers are included in cost of revenues.

#### Research and Development

Company-sponsored research and development expenses include the costs of technical activities that are useful in developing new products, services, processes or techniques, as well as expenses for technical activities that may significantly improve existing products or processes and are expensed as incurred. Grants received of \$137,000, \$1,073,000 and \$1,120,000 in the years ended December 31, 2007, 2006 and 2005, respectively, from third parties for research and development activity are recorded as reductions of expense over the term of the agreement as the related activities are conducted.

#### Clinical Studies

We accrue and expense costs for activities associated with clinical studies performed by third parties as incurred. All other costs relative to setting up clinical study sites are expensed as incurred to research and development expense. Clinical study site costs related to patient enrollment are accrued as patients are entered into the studies. Equipment that has alternative future use and is used at clinical study sites for participation in the studies are capitalized and expensed over the estimated life of the equipment.

#### Income Taxes

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. To the extent a deferred tax asset cannot be recognized under the

preceding criteria, allowances are established. At December 31, 2007 and 2006, all deferred tax assets, without offsetting liabilities in the same jurisdiction, were fully offset by a valuation allowance.

In July 2006, the FASB issued Financial Interpretation (FIN) No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), which clarifies the accounting for uncertainty in income taxes recognized in the financial statements in accordance with SFAS No. 109, Accounting for Income Taxes. FIN 48 provides that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized upon the adoption of FIN 48 and in subsequent periods. This interpretation also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. We adopted the provisions of FIN No. 48 on January 1, 2007. The adoption of FIN No. 48 did not have a material impact on our consolidated financial position or results of operations.

We accrue interest and penalties on underpayment of income taxes related to unrecognized tax benefits as a component of income tax expense in our consolidated statements of operations. No amounts were recognized for interest and penalties upon adoption of FIN 48 or during the year ended December 31, 2007.

#### Net Loss Per Share

Basic and diluted net loss per share is presented in accordance with SFAS No. 128, *Earnings per Share*. Basic net loss per share is computed by dividing consolidated net loss by the weighted-average number of common shares outstanding during the period. Shares issuable upon exercise of warrants to purchase common stock, which require little or no cash consideration from the holder, are included in basic net loss per share using the treasury stock method. A warrant to purchase an aggregate of up to 3,091,216 shares of our common stock at an exercise price of \$0.011 per share has been reflected in the calculation of basic and diluted net loss per share using the treasury stock method for periods prior to June 2006. In conjunction with our initial public offering, the warrant was automatically exercised on a cash-less basis resulting in the net issuance of 3,086,966 shares of common stock and these shares have been included in our weighted-average shares outstanding for periods presented subsequent to June 2006. Our potentially dilutive shares, which include outstanding common stock options, convertible preferred stock and warrants, other than those described in the preceding sentences, have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive. Such potentially dilutive shares are excluded when the effect would be to reduce a net loss per share.

The basic and diluted net loss per common share calculations are as follows:

	Years Ended December 31,			
	2007	2006	2005	
Net loss	\$(26,576)	\$ (8,603)	\$(15,261)	
Denominator for historical basic and diluted and pro forma basic and diluted net loss per share:			•	
Weighted-average shares outstanding	40,024	19,675	3,608	
Shares issuable upon exercise of certain warrants		1,438	3,085	
Shares used for historical basic and diluted net loss per share	40,024	21,113	6,693	
Basic and diluted net loss per share	\$ (0.66)	\$ (0.41)	\$ (2.28)	

The following table sets forth potential shares of common stock that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented (in thousands):

		51,	
	2007	2006	2005
Convertible preferred stock	_		18,123
Stock options outstanding	5,337	4,672	4,941
Warrants to purchase convertible preferred stock	_	_	177
Warrants to purchase common stock	127	171	49
Unvested common stock subject to repurchase	4	24	80

# **Operating Segments**

We are organized as a single operating segment, whereby our chief operating decision maker assesses the performance of and allocates resources to the business as a whole (see "Segment and Geographic Information" note to our consolidated financial statements).

## Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements (SFAS 157), which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 will be effective for fiscal years beginning after November 15, 2007 and we adopted SFAS 157 beginning January 1, 2008. We are currently assessing the potential impact the adoption of SFAS 157 will have on our consolidated results of operations, financial position and cash flows.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities-Including an amendment of FASB Statement No. 115 (SFAS 159). SFAS 159 expands the use of fair value accounting but does not affect existing standards which require assets or liabilities to be carried at fair value. Under SFAS 159, a company may elect to use fair value to measure accounts and loans receivable, available-forsale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred, e.g., debt issue costs. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS 159, changes in fair value are recognized in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and we will adopt SFAS 159 for our fiscal year beginning January 1, 2008. We are currently determining whether fair value accounting is appropriate for any of the eligible items and we cannot estimate the impact, if any, the adoption of SFAS 159 will have on our consolidated results of operations, financial position and cash flows.

In December 2007, the FASB issued SFAS 141 (Revised 2007), Business Combinations, or SFAS 141(R). SFAS 141(R) will change the accounting for business combinations. Under SFAS 141(R), an acquiring entity will be required to recognize all the assets acquired and liabilities assumed in a transaction at the acquisition-date fair value with limited exceptions. SFAS 141(R) will change the accounting treatment and disclosure for certain specific items in a business combination. SFAS 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Accordingly, any business combinations we engage in will be recorded and disclosed following existing GAAP until January 1, 2009. We expect SFAS 141(R) will have an impact on accounting for business combinations once adopted but the effect is dependent upon acquisitions at that time.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements—An Amendment of ARB No. 51, or SFAS 160. SFAS 160 establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. We have not completed our evaluation of the potential impact, if any, of the adoption of SFAS 160 on our consolidated financial position, results of operations and cash flows.

# 2. Acquisitions

## CardioSpectra Acquisition

On December 18, 2007, pursuant to the Agreement and Plan of Merger dated December 7, 2007, we entered into a merger agreement with CardioSpectra, Inc. (CardioSpectra), a privately-held Texas corporation, whereby Corazon Acquisition, Inc., a wholly-owned merger subsidiary of Volcano, merged with and into CardioSpectra, with CardioSpectra continuing as the surviving corporation and a wholly-owned subsidiary of Volcano. The acquisition is being accounted for as an asset purchase in accordance with SFAS No. 141.

We acquired all of the outstanding equity interests in CardioSpectra for \$26.7 million consisting of \$25.2 million in cash, plus estimated expenses. Additional payments up to an aggregate of \$38.0 million are due in the event certain milestones set forth in the Merger Agreement are achieved. The milestone payments are payable, at our sole discretion, in cash, shares of our common stock, or a combination of both and will be accounted for if and when the milestone payments have become payable. If we do issue shares of our common stock in full or partial payment of any milestone payment, the shares will be valued using a trailing 10-trading day average closing price over a period ending shortly before we inform the CardioSpectra shareholders of our determination to issue shares. Additionally, we incurred \$1.2 million in acquisition-related costs. The acquisition of CardioSpectra's OCT technology is expected to complement our existing product offerings and further enhance our position as an imaging technology leader in the field of interventional medicine. The results of operations for the period from December 18, 2007 to December 31, 2007 are included in our consolidated results of operations, financial position and cash flows.

The table below summarizes the estimated fair value of assets acquired and liabilities assumed as of the acquisition date as follows (in thousands):

	December 18, 2007
Current Assets:	
Cash	\$ 24
Prepaid expenses and other current assets	118
Total current assets	142
Equipment	132
Intangible assets(1)	274
In-process research and development(2)	26,188
Total assets acquired	\$ 26,736
Current liabilities:	
Accounts payable	\$ 316
Accrued compensation	40
Other accrued liabilities	82
Total current liabilities	438
Total liabilities acquired	438
Net assets acquired	\$ 26,298

<sup>(1)</sup> Intangible assets acquired consisted entirely of assembled workforce, which is being amortized over 4 years.

(2) In December 2007, in-process research and development was recorded as expense in our consolidated statement of operations.

Subject to the terms of the Merger Agreement, the milestone payments are payable as follows:

- \$11 million of the milestone payments to be paid upon approval by applicable US, Japanese or European regulators of a first generation OCT system on or before December 31, 2009;
- \$10 million of the milestone payments to be paid upon applicable US regulatory approval of a productized version of the first generation OCT system on or before December 31, 2010;
- \$10 million of the milestone payments to be paid upon cumulative cash sales totaling \$10 million from commercial sales of OCT products, so long as such cumulative cash sales are attained prior to the date that is 3 years after the date on which the applicable US regulatory approval described in the second bullet point above was obtained (if such approval was obtained on or before December 31, 2010) or otherwise on or before December 31, 2013; and
- \$7 million of the milestone payments to be paid upon cumulative cash sales totaling \$25 million from commercial sales of OCT products, so long as such cumulative cash sales are attained prior to the date that is 4 years after the date on which the applicable US regulatory approval described in the second bullet point above was obtained (if such approval was obtained on or before December 31, 2010) or otherwise on or before December 31, 2014.

We will use commercially reasonable efforts to cause the milestones to occur. However, if we reasonably determine that a technical failure or commercial failure has occurred with respect to all or a part of the OCT program, we may, at our sole discretion, terminate all or part of the OCT cardiovascular program.

At the closing of the merger, \$2.5 million of the aggregate merger consideration was contributed to an escrow fund which will be available for 12 months to indemnify us and related indemnitees for certain matters, including breaches of representations and warranties and covenants included in the merger agreement. The escrow fund is subject to a \$100,000 deductible in the case of breaches of representations and warranties. Once the escrow fund has been exhausted or released, we have the right to withhold and deduct amounts for any indemnification claims from milestone payments otherwise payable by us.

# Acquisition of IVUS Technology

In July 2003, we entered into a license agreement whereby we were granted the rights to certain IVUS technology and patents for total consideration of €5,661,000 (\$6,534,000 using exchange rates in effect at that time). The consideration was comprised of an upfront payment of €3,000,000 and four annual payments of €725,000 payable on the anniversary date of the agreement commencing in July 2004. Closing costs for the purchase were \$87,000. This license fee is recorded as an intangible asset and is being amortized over the estimated useful life of the patents and technology of 10 years. In addition, during the license period, the license agreement requires that we pay royalties based upon the number of units we sell using the licensed technology. The seller has also agreed to assist us in commencing our business to use the acquired technology and manufacture and sell the related products (see "Commitments and Contingencies" note to our consolidated financial statements).

# Jomed Acquisition

Also in July 2003, we completed the Jomed Acquisition (see "Summary of Significant Accounting Policies" note to our consolidated financial statements). The fair values of the net assets acquired and the liabilities assumed have been estimated for purposes of allocating the purchase price and were determined pursuant to an independent valuation. The aggregate purchase price of \$35.8 million was paid in cash and included closing costs of \$2.5 million. In addition, we assumed liabilities of \$2.8 million. Developed technology and customer relationship intangible assets of \$14.1 million are being amortized over a period of six and one-half years using the straight-line method, which reflects the estimated life of the purchased intangibles without any post-purchase enhancements or synergies with our other products.

# 3. Financial Statement Details

# Accounts Receivable, Net

Accounts receivable, net consists of the following (in thousands):

	December 31,				
		2007	2006		
Trade accounts receivable	\$	28,114	\$	21,776	
Less: allowance for doubtful accounts		138		201	
Total	\$	27,976	\$	21,575	

The change in the allowance for doubtful accounts for the years ended December 31, 2007, 2006 and 2005, respectively, is summarized in the following table (in thousands):

	Years Ended December 31,				er 31,	
		2007	2	2006		2005
Balance at beginning of year	\$	201	\$	158	\$	118
Additions charged to selling, general and administrative expense, net of recoveries		(79)		70		70
Write-offs				(40)		(21)
Foreign currency translation adjustments	_	16		13	_	<u>(9</u> )
Balance at end of year	<u>\$</u>	138	<u>\$</u>	201	<u>\$</u>	158

# Inventories

Inventories consist of the following (in thousands):

•		,		
		2007		2006
Finished goods	\$	7,010	\$	5,302
Work-in-process		5,337		2,529
Raw materials		8,896		5,592
Total	\$	21,243	\$	13,423

# Property and Equipment

Property and equipment consists of the following (in thousands):

	December 31,				
		2007		2006	
Equipment	\$	11,371	\$	9,269	
Medical diagnostic equipment		15,016		9,210	
Leasehold improvements		1,490		1,613	
Purchased software		1,803		973 .	
Construction-in-progress		395		700	
		30,075		21,765	
Accumulated depreciation and amortization	_	(16,383)		(12,432)	
Total	\$	13,692	\$	9,333	

The amount reflected in equipment cost at December 31, 2007 and 2006 includes assets under capital lease of \$335,000 and \$230,000, respectively. At December 31, 2007 and 2006, the net book value of assets under capital leases was \$132,000 and \$62,000, respectively.

Depreciation expense and amortization of leasehold improvements for the years ended December 31, 2007, 2006 and 2005 was \$4,835,000, \$5,363,000 and \$4,048,000, respectively. Included in these amounts, was amortization expense for leased equipment for the years ended December 31, 2007, 2006 and 2005 of \$35,000, \$39,000 and \$53,000, respectively.

In 2005, we recorded an impairment charge of \$360,000 to reduce certain medical diagnostic equipment to its estimated net realizable value (See "Impairment of Long-lived Assets" note to our consolidated financial statements).

#### 4. Debt and Credit Facilities

Our debt consists of the following (in thousands):

		1,		
	2007			2006
Note payable, non-interest bearing, payable in four annual payments of €725,000, matured in 2007(a)	\$		\$	905
Term loan B, bearing interest at 13.0% per annum, payable monthly, matured in October 2007(b)		_		528
Term loan C, bearing interest at 13.7% per annum, payable monthly, maturing in February 2008(b)		64		229
Capital lease obligations(c)		134		108
		198		1,770
Less: Current portion		(120)		(1,654)
Unamortized debt discount				(50)
Long-term debt	\$	78	\$	66

# Short-Term Debt

Revolving Credit Facility—In July 2003, to provide working capital and for general corporate purposes, we entered into a revolving credit facility agreement with a bank. In May 2007, the credit facility expired as scheduled.

# Long-Term Debt

- (a) Note Payable—In July 2003, we entered into a license agreement whereby we were granted the rights to certain IVUS patents and technology (see "Commitments and Contingencies" note to our consolidated financial statements). As part of the agreement, we entered into a non-interest bearing note, which required that we make four annual payments of €725,000 (totaling \$3,347,000 at inception). The present value of these deferred payments were recorded at the time of the acquisition utilizing a 4.75% discount rate. The resulting imputed interest of €314,000 (\$363,000 at inception) was being charged to expense over the four-year term of the note. The euro-denominated liability was translated into U.S. dollars at period-end exchange rates and any exchange rate fluctuations were recorded as foreign currency transaction gains or losses and were included in exchange rate gain (loss) in the consolidated statements of operations.
- (b) Term Loans—In September 2003, to provide working capital and for general corporate purposes, we entered into a loan and security agreement with a venture capital company providing for a maximum borrowing of \$7,000,000.
- (c) Capital Lease Obligations—We lease certain equipment under capital lease arrangements (see "Commitments and Contingencies" note to our consolidated financial statements).

## Key Covenants

Our debt agreements include several covenants that place restrictions on the incurrence of debt and liens, capital expenditures, the payment of dividends and mergers. We are in compliance with all covenants and limitations included in the provisions of our loan and credit agreements as of December 31, 2007 and 2006.

# Debt Maturities

Excluding capital lease obligations (see "Commitments and Contingencies" note to our consolidated financial statements), the \$64,000 remaining outstanding balance of our term loan is scheduled to be repaid by December 31, 2008.

#### 5. Financial Instruments

Cash, Cash Equivalents and Short Term Investments. Short-term investments have been classified as available-for-sale securities. At December 31, 2007, our cash and cash equivalents plus short-term available-for-sale investments were as follows (in thousands):

	Cost		Unre	ross ealized ains	Unro Lo Less	ross ealized osses Than Ionths	Unr Le 12 Me	ross ealized osses onths or onger	Esti	mated Fair Value
Non interest bearing cash	\$	4,021	\$	_	\$	_	\$	_	\$	4,021
Money market funds		64,199		_		_				64,199
U.S. corporate securities		120,843		62		(7)				120,898
Total	\$	189,063	\$	62	\$	(7)	\$		\$	189,118

As of December 31, 2007, all of our investments mature within one year. These investments are recorded at their estimated fair value with unrealized gains or losses reported as a separate component of accumulated other comprehensive loss.

#### 6. Intangible Assets

Intangible assets consist of developed technology, customer relationships, assembled workforce, licenses, and patents and trademarks, which are amortized using the straight-line method over periods ranging from three to ten years, representing the estimated useful lives of the assets. During the year ended December 31, 2007, we recorded intangible asset additions of \$232,000 related to internally developed patents and trade marks and \$274,000 related to assembled workforce acquired as part of the CardioSpectra Acquisition (see "Acquisitions" note to our consolidated financial statements).

During the year ended December 31, 2006, we recorded intangible asset additions of \$419,000, related to internally developed patents and trademarks. During the year ended December 31, 2005, we recorded intangible asset additions of \$468,000, which is comprised of \$23,000 in acquired technology-based and customer-related assets, \$16,000 for acquired patents, \$264,000 for internally developed patents and trademarks, \$160,000 for acquired licenses and \$5,000 for other intangible assets.

Intangible assets subject to amortization, by major class, consist of the following (in thousands):

•		Cost	cumulated ortization		Net	Weighted- Average Life
Developed technology	\$	12,469	\$ 8,692	\$	3,777	6.3
Licenses		7,034	3,440		3,594	9.8
Customer relationships		1,674	1,099		575	8.5
Patents and trademarks		1,601	436		1,165	9.3
Assembled workforce		274			274	4.0
	\$	23,052	\$ 13,667	<u>\$</u>	9,385	7.4

	December 31, 2006						
		Cost		umulated ortization		Net	
Developed technology	\$	12,469	\$	6,714	\$	5,755	
Licenses		7,034		2,721		4,313	
Customer relationships		1,674		901		773	
Patents and trademarks		1,369		264		1,105	
•	<u>\$</u>	22,546	\$	10,600	<u>\$</u>	11,946	

Amortization of intangibles for the years ended December 31, 2007, 2006 and 2005 was \$3,067,000, \$3,117,000 and \$3,052,000, respectively.

Intangible amortization expense for the next five years based on December 31, 2007 intangible assets is expected to be as follows (in thousands):

2008	\$ 3,172
2009	3,172
2010	996
2011	996
2012	871

#### 7. Impairment of Long-Lived Assets

In 2005, based upon the estimated discounted future cash flows to be realized from the assets, we recorded an impairment charge of \$360,000 to reduce certain medical diagnostic equipment to its estimated net realizable value. The impairment charge is recorded in cost of revenues in our consolidated statement of operations for the year ended December 31, 2005.

#### 8. Commitments and Contingencies

#### Litigation

We are a party to various claims in the normal course of business. Legal fees and other costs associated with such actions are expensed as incurred and were not material in any period reported. Additionally, we assess, in conjunction with our legal counsel, the need to record a liability for litigation and contingencies. Reserve estimates are recorded when and if it is determined that a loss related matter is both probable and reasonably estimable. We believe that the ultimate disposition of these matters will not have a material impact on our consolidated results of operations, financial position or cash flows.

#### **Collaboration Agreements**

In August 2005, we entered into a development and license memorandum of understanding (MOU), which was formalized into an agreement dated May 10, 2006, whereby a third party will develop technology and license to us such technology. Costs incurred through December 31, 2007 totaled \$738,000 recorded as research and development expense. Under the agreement, we are also required to pay a royalty for each product sold using the licensed technology. As of December 31, 2007, our remaining obligation pursuant to the agreement is \$225,000 and payment of such amount is dependant upon completion by the third party of certain performance milestones.

In September 2004, we signed a collaboration agreement with a third party in which the third party will conduct clinical studies concerning a natural history study of lesions using our products. We have agreed to provide a total of \$1,500,000 in the form of products, product related expenses and cash in connection with the conduct of the clinical studies. As of December 31, 2007, our remaining obligation pursuant to the clinical studies was approximately \$50,000. These costs are recorded as research and development expenses in the period they are incurred.

In October 2007, we signed a clinical research support agreement with a third party in which the third party will conduct clinical studies concerning drug eluting stents. We have agreed to provide a total of \$4,550,000 to fund clinical study activities. There has been no activity related to the clinical study and, consequently, as of December 31, 2007, no amounts have been paid.

#### Licenses

In July 2003, we entered into a license agreement whereby we were granted the rights to certain IVUS technology and patents for total consideration of €5,661,000 (\$6,534,000). The consideration is comprised of an upfront payment of €3,000,000 and four annual payments of €725,000 payable on the anniversary date of the agreement commencing in July 2004 (see "Debt and Credit Facilities" note to our consolidated financial statements). Closing costs for the purchase were \$87,000. This license fee is recorded as an intangible asset and is being amortized over the estimated useful lives of the patents and technology of 10 years. In addition, we are paying royalties during the license period related to the sale of our products using the licensed technology and are calculated on a per unit basis using a sliding scale. Minimum aggregate royalty payments of €500,000 (approximately \$730,000 at December 31, 2007 currency exchange rates) are required in each of the twelve month periods ended June 30, 2008 and June 30, 2009. During the years ended December 31, 2007 and 2006, royalty expense related to the use of this licensed technology totaled \$243,000 and \$9,000, respectively. In the year ended December 31, 2005, there were no sales of products using this licensed technology and therefore no amounts relative to royalties were accrued or paid.

In April 2002, we entered into a license agreement with a medical research clinic whereby we were granted a license to certain patents and technology. The agreement requires the payment of a license fee of \$200,000, which was made in April 2002. In addition, we are required to make milestone payments of \$125,000 upon receiving both U.S. and E.U. regulatory clearances, or upon the first commercial sale within each territory, whichever event occurs first. In 2004 and 2005, we received U.S. and E.U. regulatory clearance, respectively and made the required payments of \$125,000 relative to each regulatory clearance. We are also required to pay a royalty based on a percentage of net sales, as defined in the agreement, of products using the licensed technology. The license fees paid of \$450,000 are recorded as an intangible asset and have been amortized over the original estimated useful life of the underlying technology of five years. During the year ended December 31, 2005, sales of licensed products commenced and in the years ended December 31, 2007, 2006 and 2005, we recorded royalty expense of \$278,000, \$225,000 and \$195,000, respectively, in cost of revenues.

We have entered into certain other licensing agreements with third parties which require us to make annual royalty payments based on either a minimum dollar amount or as a percentage of net sales, which ever is higher. None of these other agreements are material to our consolidated results of operations or financial condition.

#### Leases

We lease our domestic and foreign facilities and certain office equipment under non-cancelable capital and operating lease agreements, which are non-cancelable at various dates through 2009 and expire at various dates through 2013. In addition to the minimum future lease commitments presented below, the leases generally require

that we pay property taxes, insurance, maintenance and repair costs. Certain leases also contain escalation clauses and renewal option clauses calling for increased rents. Where a lease contains an escalation clause or a concession such as a rent holiday, rent expense is recognized in accordance with FASB Technical Bulletin 85-3, Accounting for Operating Leases with Scheduled Rent Increases, using the straight line method over the term of the lease.

At December 31, 2007, future minimum lease commitments under non-cancelable leases are as follows (in thousands):

Year Ending December 31,	Ca	pital	Oj	perating
2008	\$	64	\$	2,349
2009		55		1,680
2010		25		183
2011		2		
2012				_
Thereafter				
Net minimum lease payments		146	\$	4,212
Less:				
Amounts representing interest		12		
Current		56		
Long-term	\$	78		

Total rental expense was \$2.4 million, \$2.0 million and \$1.6 million for the years ended December 31, 2007, 2006 and 2005, respectively.

#### Purchase Commitments

We have obligations under non-cancelable purchase commitments for inventory, primarily raw materials. As of December 31, 2007, the future minimum payments under these non-cancelable purchase commitments, all requiring payment in 2008, totaled \$9,885,000.

# Indemnification

Our supplier, distributor and collaboration agreements generally include certain provisions for indemnification against liabilities if our products are recalled, infringe a third-party's intellectual property rights or cause bodily injury due to alleged defects in our products. In addition, we have agreements with our Board of Directors indemnifying them against liabilities arising from actions taken against us. To date, we have not incurred any material costs as a result of such indemnifications and have not accrued any liabilities related to such obligations in the accompanying consolidated financial statements.

# 9. Convertible Preferred Stock

As of December 31, 2005, convertible preferred stock consists of the following (in thousands):

	Shares			ggregate
	Authorized	Issued and Outstanding	Lid	quidation eference
Series A	2,304	2,304	\$	2,304
Series B	15,143	14,949		44,846
Series C	2,662	2,662	_	15,364
	20,109	19,915	<u>\$</u>	62,514

During 2001, we entered into agreements with several investors who collectively purchased 2,303,850 shares of our designated Series A Convertible Preferred Stock (Series A Preferred Stock) at \$1.00 per share in exchange for cash of \$2,304,000.

During 2002, we entered into agreements with several investors who collectively purchased 8,000,000 shares of our Series B Preferred Stock at \$3.00 per share in exchange for the conversion of \$1,900,000 in promissory notes and \$22,045,000 in cash, net of issuance costs of \$55,000.

In July 2003, we entered into agreements with several investors who collectively purchased 6,698,835 shares of our Series B Preferred Stock at \$3.00 per share in exchange for \$20,026,000 in cash, net of issuance costs of \$71,000. The proceeds were used to fund the Jomed Acquisition (see "Acquisitions" note to our consolidated financial statements). Included in the shares purchased were 1,166,667 shares purchased by a related party, Medtronic Inc., for \$3,500,000 (see "Related Parties" note to our consolidated financial statements). In November 2003, an additional 166,667 shares of Series B Preferred Stock were purchased by an investor at \$3.00 per share in exchange for \$500,000 in cash.

In March 2004, we sold 83,334 shares of Series B Preferred Stock in a private placement for \$3.00 per share. We received net cash proceeds related to this offering of \$245,000, net of issuance costs of \$5,000.

In February 2005, we sold 2,662,754 shares of designated Series C Convertible Preferred Stock (Series C Preferred Stock) in a private placement for \$5.77 per share. We received net cash proceeds related to this offering of \$15,106,000, net of issuance costs of \$258,000.

On June 15, 2006, in connection with our initial public offering, all of the Series A, Series B, and Series C convertible preferred stock outstanding were automatically converted into 18,123,040 shares of common stock at a 1-to-0.91 conversion ratio.

# 10. Stockholders' Equity

In May 2006, our stockholders approved a resolution to increase the number of authorized shares of our common stock to 250,000,000, which became effective upon the completion of our initial public offering. In May 2006 and June 2007, our stockholders approved increases in the number of shares subject to our 2005 equity compensation plan by 2,272,727 shares and 3,500,000 shares, respectively, to a total of 11,662,558. As of December 31, 2007, we have reserved 9,332,104 shares, 500,000 shares and 127,400 shares of our common stock for the issuance of options under our stock option plans, the issuance of shares under our employee stock purchase plan and the exercise of common stock warrants, respectively.

# Stockholders Rights Plan

In May 2006, our stockholders approved a stockholder rights plan and a classified board of directors with staggered terms of election. Pursuant to the stockholder rights plan, we declared and paid a dividend of one right for each share of common stock. Unless redeemed prior to the time the rights are exercised, upon the occurrence of certain events, the rights will entitle the holders to receive shares of our preferred stock, or shares of an acquiring entity.

The increase to the authorized shares, the stockholder rights plan and the classified board of directors became effective upon the consummation of our initial public offering.

# Public Offerings of our Common Stock

On June 15, 2006, we completed an initial public offering in which 7,820,000 shares of our common stock was sold to the public at an offering price of \$8.00 per share. The initial public offering resulted in net proceeds of \$54.5 million, after deducting offering expenses and underwriting discounts and commissions. Of the net proceeds, \$29.2 million was used to repay our senior subordinated debt, as required by its terms and \$750,000 was used to pay the outstanding balance of our short-term debt. In conjunction with the offering, all of our outstanding shares of preferred stock were converted into 18,123,040 shares of our common stock immediately prior to the closing of the offering and certain warrants to purchase 3,103,943 shares of our common stock were by their terms, automatically

exercised on a cash-less basis upon the closing of the offering, resulting in the net issuance of 3,097,943 shares of our common stock.

On December 12, 2006, we completed a follow-on offering in which 3,500,000 shares of our common stock were sold by the Company and 4,000,000 shares were sold by certain selling stockholders, including officers of the Company. In addition, we sold 795,000 shares under an over-allotment option exercised by the underwriters. The follow-on offering, including the exercise of the over-allotment option, resulted in net proceeds to the Company of \$66.8 million, after deducting offering expenses and underwriting discounts and commissions.

On October 23, 2007, we completed a follow-on offering in which 8,050,000 shares of our common stock were sold by the Company, including 1,050,000 shares under an over-allotment option exercised by the underwriters. The follow-on offering, including the exercise of the over-allotment option, resulted in net proceeds to the company of \$122.8 million, after deducting offering expenses and underwriting discounts and commissions.

# Warrants

As of December 31, 2007, there is a warrant outstanding to purchase 127,400 shares of our common stock at a price of \$3.30 per share. The warrant is immediately exercisable by the holder and expires on September 30, 2011.

#### Stock-Based Compensation

As of December 31, 2007, we have granted options under the 2005 Equity Compensation Plan (the 2005 Plan) and the 2000 Long Term Incentive Plan (the 2000 Plan) under which a maximum aggregate number of 11,662,558 shares of our common stock may be issued or transferred to our employees, non-employee directors and consultants. Effective October 2005, all options will be granted under the 2005 Plan. Options previously granted under the 2000 Plan that are cancelled or expire will increase the shares available for grant under the 2005 Plan. The terms of the grant vary as described below.

The 2005 Plan provides for the grant of incentive stock options, non-qualified stock options, stock awards (including rights to purchase restricted stock) and stock appreciation rights to eligible recipients. Recipients of incentive stock options shall be eligible to purchase shares of our common stock at an exercise price no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the Plan is seven years. For an initial grant to an employee, the options generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years. For subsequent grants to an employee, the options generally vest monthly over a four-year term. We may grant options that are exercisable immediately regardless of the vesting status of the option with us retaining a right to repurchase exercised unvested shares at the original exercise price of the option. As of December 31, 2007, 3,981,646 shares remained available to grant.

The 2000 Plan provided for the grant of incentive stock options, non-statutory stock options, phantom stock and rights to purchase restricted stock to eligible recipients. Recipients of incentive stock options shall be eligible to purchase shares of our common stock at an exercise price no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the Plan is 10 years. The options generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years. All option grants are exercisable immediately regardless of the vesting status of the option with us retaining a right to repurchase exercised unvested shares at the original exercise price of the option. In January 2005, we accelerated vesting on certain non-employee options representing options to purchase 85,545 shares of our common stock. In connection with accelerating the vesting of these options, we recorded charges totaling \$412,000 in the accompanying statement of operations. Of that amount, \$34,000 was recorded in research and development and \$378,000 was recorded in selling, general and administrative.

For the year ended December 31, 2005, we recorded deferred stock compensation of \$1,239,000, in connection with the grant of stock options to employees. Deferred stock compensation reflects the difference between the exercise price of the options and the estimated fair value of the common stock at the date of grant. The estimated fair value was determined based on the business factors underlying the value of our common stock on the date of grant. These amounts were recorded as a component of stockholders' equity (deficit) and were being amortized to operating

expense over the vesting period of the options, generally four years using the straight-line method. During the year ended December 31, 2005, we reversed stock compensation expense of \$25,000 relating to the forfeiture of unvested employee stock options. For the year ended December 31, 2005, we recognized \$1,102,000 of net stock compensation expense related to the amortization of deferred employee stock compensation. Effective with our adoption of SFAS No. 123(R) on January 1, 2006, we reversed deferred stock-based compensation recorded as of that date. Accordingly, there was no deferred stock-based compensation recorded as of December 31, 2006.

The following table sets forth stock-based compensation expense included in our Consolidated Statements of Operations (in thousands):

	Years Ended December 31,						
	2007		2006		2005		
Cost of revenues	\$	621	\$	348	\$	258	
Selling, general and administrative	\$	4,919	\$	2,238	\$	1,267	
Research and development	\$	1,151	\$	609	\$	423	

Included in our stock-based compensation expense are \$341,000, \$434,000 and \$736,000 of stock-based compensation expense related to non-employees in the years ended December 31, 2007, 2006 and 2005, respectively. In addition, \$232,000 of stock-based compensation expense related to the employee stock purchase plan was recorded in the year ended December 31, 2007.

On January 1, 2006, we adopted SFAS No. 123(R) which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors based on estimated fair values. In March 2005, the Securities and Exchange Commission issued SAB No. 107 relating to SFAS No. 123(R) and we have applied the provisions of SAB No. 107 in our adoption of SFAS No. 123(R). Prior to January 1, 2006, we accounted for share-based payments using the intrinsic value method in accordance with APB No. 25, and related Interpretations, as permitted by SFAS No. 123. In accordance with APB No. 25, stock-based compensation expense had been recognized only when the fair market value of our stock options granted to employees and directors was greater than the exercise price of the underlying stock at the date of grant.

We adopted SFAS No. 123(R) using the modified-prospective-transition method. Under that transition method, stock-based compensation cost recognized in the year ended December 31, 2006 includes stock-based compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and stock-based compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). SFAS No. 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods. SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In our pro forma information required under SFAS No. 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred. In accordance with the modified-prospective transition method, prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123(R).

As a result of adopting SFAS No. 123(R) on January 1, 2006, our net loss for the years ended December 31, 2007 and 2006 is \$5.1 million and \$1.8 million higher, respectively, than if we had continued to account for stock-based compensation under APB No. 25 as we did in 2005. The table below summarizes the effect on basic and diluted earnings per share of adopting SFAS No. 123(R):

	December 31,			·
		2007	_	2006
Loss per share, as reported:				
Basic and diluted	\$	(0.66)	\$	(0.41)
Adjusted earnings (loss) per share(1):				
Basic and diluted	\$	(0.53)	\$	(0.32)

<sup>(1)</sup> Adjusted earnings per share if we had not adopted SFAS No. 123(R).

We have not recognized, and we do not expect to recognize in the near future, any tax benefit related to employee stock-based compensation cost as a result of the full valuation allowance its net deferred tax assets and its net operating loss carryforwards. The total compensation cost capitalized in inventory was \$256,000 and \$152,000 as of December 31, 2007 and 2006, respectively.

Stock option activity is summarized as follows for the years ended December 31, 2007, 2006 and 2005:

	Shares	A E	eighted- werage xercise Price
Outstanding, December 31, 2004	3,718,901	\$	0.30
Granted below estimated fair value (weighted-average fair value of \$4.36)	271,024	\$	1.19
Granted at estimated fair value (weighted-average fair value of \$4.29)	1,464,819	\$	6.70
Exercised	(180,998)	\$	0.35
Canceled and expired	(332,908)	\$	1.95
Outstanding, December 31, 2005	4,940,838	\$	2.13
Granted at estimated fair value	364,245	\$	11.45
Exercised	(466,023)	\$	0.38
Canceled and expired	(166,652)	\$	3.69
Outstanding, December 31, 2006	4,672,408	\$	2.98
Granted at estimated fair value	1,967,955	\$	18.97
Exercised	(1,151,996)	\$	1.46
Canceled and expired	(151,009)	\$	13.76
Outstanding, December 31, 2007	5,337,358	\$	8.90

Options outstanding as of December 31, 2007 are summarized as follows:

	Options (	Jutstanding and Exer	rcisabl	le	Vested O	ptions	5
Range	Weighted- Average Weighted- Remaining Average Number Contractual Life Exercise Outstanding (in years) Price		verage xercise	Number Outstanding	A E	eighted- verage xercise Price	
\$0.11	311,218	4.3	\$	0.11	311,218	\$	0.11
\$0.33	1,475,018	6.0	\$	0.33	1,343,703	\$	0.33
\$0.83 - \$6.49	1,155,263	7.4	\$	5.14	700,635	\$	4.91
\$8.36 - \$18.44	829,594	5.7	\$	12.51	226,310	\$	10.12
\$19.11	986,351	6.1	\$	19.11	226,086	\$	19.11
\$19.77 - \$21.07	579,914	6.4	\$	20.36	34,070	\$	20.88
\$0.11 to \$21.07	5,337,358	6.2	\$	8.90	2,842,022	\$	3.96

A summary of the status of our non-vested shares as of December 31, 2007 and changes during the year ended December 31, 2007 is as follows:

	Shares	A Grant	eighted- verage Date Fair Value
Non-vested shares at December 31, 2006	1,891,033	\$	3.94
Grants of options	1,967,955	\$	9.18
Vested	(1,208,347)	\$	4.72
Forfeitures or expirations	(151,009)	\$	7.36
Non-vested shares at December 31, 2007	2,499,632	\$	7.48

Option activity for the year ended December 31, 2007 is as follows:

	Shares	A E	eighted- verage xercise Price	Weighted- Average Remaining Contractual Life (in years)	Aggregate intrinsic value (In thousands)
Outstanding at December 31, 2006	4,672,408	\$	2.98		
Grants of options	1,967,955	\$	18.97		
Exercises	(1,151,996)	\$	1.46		
Forfeitures or expirations	(151,009)	\$	13.76		
Outstanding and exercisable at December 31, 2007	5,337,358	\$	8.90	6.2	\$31,786
Vested and expected to vest as of December 31, 2007	5,215,914	\$	8.77	6.2	\$31,531

As required by SFAS No. 123(R), we made an estimate of expected forfeitures and are recognizing compensation cost only for those equity awards expected to vest.

The total intrinsic value of stock options exercised during the year ended December 31, 2007 was \$19.8 million and represents the difference between the exercise price of the option and the fair value of our common stock on the dates exercised. As of December 31, 2007, approximately \$18 million of total unrecognized compensation cost related to stock options issued to employees is expected to be recognized over a weighted average term of 3.0 years.

#### Employee Stock Purchase Plan

On June 7, 2007, our stockholders approved the adoption of our 2007 Employee Stock Purchase Plan (the "Purchase Plan"). The Purchase Plan provides for the purchase of up to an aggregate of 500,000 shares of common stock of the company. Beginning in 2008, common stock reserved for under the Purchase Plan automatically increases by the lower of 1½% of our outstanding common stock or 600,000 shares on the first day of January of each year. The Purchase Plan provides eligible employees the opportunity to purchase shares of Volcano Corporation common stock at the lower of up to 85% of the fair market value on the first or last day of the applicable offering period, by having withheld from their salary an amount up to 15% of their compensation, without paying brokerage fees or commissions on purchases. Our Purchase Plan is deemed to be compensatory, and therefore, Purchase Plan expense under SFAS 123(R) has been included in our consolidated statements of operations for the year ended December 31, 2007. The fair value of those purchase rights granted during the year ended December 31, 2007, as defined by SFAS 123(R), was \$4.70.

Volcano Corporation pays for the program's administrative expenses. No employee may purchase more than \$25,000 worth of common stock (calculated at the time the purchase right is granted) in any calendar year, nor may purchase more than 750 shares in any six-month purchase period. The Purchase Plan is administered by the Compensation Committee of the Board of Directors and the first offering period began on September 1, 2007. As of

December 31, 2007, no shares of common stock had been issued under the Purchase Plan and there were a total of 500,000 shares of common stock reserved for issuance under the Purchase Plan.

#### 11. Income Taxes

The provisions for income tax expense are as follows (in thousands):

		Years Ended December 31,				
		2007	2	2006		005
Current:						
Federal	\$	_	\$	_	\$	
State		133		35		50
Foreign	_	391		263		20
	\$	524	<u>\$</u>	298	<u>\$</u>	<u>70</u>

Losses before income taxes include losses relating to non-U.S. operations of \$2,000,000, \$2,900,000 and \$2,700,000 in the years ended December 31, 2007, 2006 and 2005, respectively.

Provisions for income taxes in the accompanying consolidated statements of operations differ from the expense calculated by applying the U.S. federal statutory income tax rate of 35% to loss before provision for income taxes due to the following (in thousands):

		Year 2007	s Enc	led December 2006	31,	2005
U.S. federal statutory income tax benefit	\$	(9,118)	\$	(2,907)	\$	(5,317)
State income tax benefit, net of federal income tax expense		(173)		(524)		(393)
Valuation allowance		725		3,308		6,163
Foreign tax rate differential		281		445		(142)
Credits		(587)		(414)		(401)
In-process research and development		9,166		_		_
Other	_	230		390		160
	\$	524	\$	298	\$	70

The components of our deferred tax assets are as follows (in thousands):

		December 31,		
		2007		2006
Deferred tax assets:				
Net operating loss carryovers	\$	17,654	\$	18,335
Tax credit carryovers		3,733		3,236
Depreciation and amortization		1,939		1,937
Accruals		4,048		1,285
Deferred revenue		527		623
Other, net		1,396		1,340
Total deferred tax assets		29,297		26,756
Less valuation allowance		(29,297)		(26,756)
	<u>\$</u>		\$	

A valuation allowance has been established to offset deferred tax assets, as realization of such assets is uncertain.

As a result of certain realization requirements of SFAS 123(R), the table of deferred tax assets shown above do not include certain deferred tax assets at December 31, 2007 and 2006 that arose directly from tax deductions related to

equity compensation in excess of compensation recognized for financial reporting. Equity will be increased by approximately \$4,300,000 if and when such deferred tax assets are ultimately realized. We use tax law ordering for purposes of determining when excess tax benefits have been realized.

At December 31, 2007, we have federal and state net operating loss carryforwards of approximately \$48,000,000 and \$25,000,000, respectively. The federal and state net operating loss carryforwards begin to expire in 2020 and 2012, respectively, unless previously utilized. In addition, we have federal and state research and experimentation tax credit carryforwards of \$2,400,000 and \$2,100,000, respectively. The federal credits begin to expire in 2022. The state credits carry forward indefinitely. Foreign net operating losses are approximately \$11,000,000 which expire beginning in 2009.

Pursuant to Internal Revenue Code Section 382, use of our net operating loss carryforwards will be limited if a cumulative change in ownership of more than 50% has occurred within a three-year period.

# 12. Segment and Geographic Information

Our chief operating decision-maker reviews financial information presented on a consolidated basis, accompanied by disaggregated information about revenues by geographic region for purposes of making operating decisions and assessing financial performance. Accordingly, we consider ourselves to be in a single reporting segment, specifically the manufacture, sale, discovery, development and commercialization of products for the diagnosis of atherosclerosis in the coronary arteries and peripheral vascular system. We do not assess the performance of our geographic regions on other measures of income or expense, such as depreciation and amortization, operating income or net income. In addition, our assets are primarily located in the United States and are not allocated to any specific region. We do not produce reports for, or measure the performance of, our geographic regions on any asset-based metrics. Therefore, geographic information is presented only for revenues.

Revenues based on geographic location are summarized in the following table (in thousands):

		Yea 2007	rs En	led December 2006	г 31,	2005
Revenues:						
United States	\$	66,411	\$	51,013	\$	40,933
Japan		35,186		30,082		33,207
Europe, the Middle East and Africa		23,995		17,765		15,294
Rest of world	_	5,022		4,188	_	2,466
	\$	130,614	\$	103,048	<u>\$</u>	91,900

#### 13. Employee Benefits

#### **Defined Contribution Plans**

We have a defined contribution 401(k) plan for our U.S. employees who are at least 21 years of age. Employees are eligible to participate in the plan beginning on the first day of the month following their first date of hire. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation or as a fixed amount per pay period. Our contributions to the plan are discretionary and no contributions were made during the three years ended December 31, 2007, 2006 and 2005. Beginning in 2008, we began matching 25% of employee contributions up to 6% of salary.

We also sponsor additional defined contribution plans for most of our European employees. Contributions under all plans were \$202,000, \$143,000 and \$104,000 in the years ended December 31, 2007, 2006 and 2005, respectively.

# 14. Quarterly Information (Unaudited)

The following table sets forth our unaudited quarterly summary consolidated statements of operations for each of the quarters for the years ended December 31, 2007 and 2006. The information for each of these quarters is unaudited and has been prepared on the same basis as our audited consolidated financial statements. This data

should be read in conjunction with our consolidated financial statements and related notes. These operating results may not be indicative of results to be expected for any future period (amounts in thousands, except per share data).

•		Quarter Ended										
2007	March 31			June 30			September 30		December 31(1)		Year Ended December 31	
Revenue	\$	29,579	)	\$	29,552	\$	31,474	\$	40,009		\$130,614	
Gross profit		18,714	1		17,236		19,189		23,916		79,055	
Operating income (loss)		656	ó		(4,938)		(2,404)		(26,460	)	(33,146)	
Net income (loss)		1,674	1		(3,855)		(652)		(23,219	)	(26,052)	
Net income (loss) per share:												
Basic	\$	0.04	ļ	\$	(0.10)	\$	(0.02)	\$	(0.53	)	\$ (0.66)	
Diluted	\$	0.04	ļ	\$	(0.10)	\$	(0.02)	\$	(0.53	)	\$ (0.66)	
Includes the following stock- based compensation expense:												
Cost of revenues	\$	112	2	\$	140	\$	181	\$	188		\$ 621	
Selling, general and administrative		923	3		1,126		1,437		1,433		4,919	
Research and development		,208	3		217		359		367	٠.	1,151	
					Quarter l	Ende	d			Ye	ar Ended	
2006	M	larch 31		Ju	ne 30	Sep	tember 30	Dece	mber 31		cember 31	
Revenue	\$	19,872	\$		25,863	\$	27,782	\$	29,531	\$	103,048	
Gross profit		11,652			14,395		17,222		18,064		61,333	
Operating income (loss)		(5,320)			(2,312)		707		604		(6,321	

			Year Ended								
2006		March 31		June 30		September 30		December 31		December 31	
Revenue	\$	19,872	\$	25,863	\$	27,782	\$	29,531	\$	103,048	
Gross profit		11,652		14,395		17,222		18,064		61,333	
Operating income (loss)		(5,320)		(2,312)		707		604		(6,321)	
Net income (loss)		(6,374)		(4,163)		501		1,433		(8,603)	
Net income (loss) per share:											
Basic	\$	(0.93)	\$	(0.41)	\$	0.02	\$	0.04	\$	(0.41)	
Diluted	\$	(0.93)	\$	(0.41)	\$	0.01	\$	0.04	\$	(0.41)	
Includes the following stock-based compensation expense:											
Cost of revenues	\$	68	\$	68	\$	103	\$	109	\$	348	
Selling, general and administrative		506		601		573		558		2,238	
Research and development		115		127		133		234		609	

<sup>(1)</sup> During the fourth quarter of 2007, we recorded a \$26.2 million write-off of in-process research and development that was purchased as part of the December 18, 2007 acquisition of CardioSpectra.

#### 15. Related Parties

# Medtronic, Inc. and Its Affiliates

Medtronic was an investor in our Series B Preferred Stock. In connection with our initial public offering in June 2006, their investment in our preferred stock automatically converted into shares of our common stock.

We have collaborations with Medtronic, Inc. and certain of its affiliates (collectively, Medtronic). In July 2003, we entered into agreements with Medtronic which provided Medtronic with a license to manufacture and market certain products incorporating our IVUS technology, technical guidance to develop products covered by the license and certain supply rights related to the products covered by the license. We were paid a \$2,500,000 license fee by

Medtronic in exchange for the fully paid, royalty-free, perpetual, irrevocable, worldwide license. The license fee has been deferred and is being recognized as revenue over the estimated 10-year term of the agreement. The amount recorded in revenues totaled \$250,000 during each of the years ended December 31, 2007, 2006 and 2005, respectively. At December 31, 2007, the amount deferred was \$1,375,000, of which \$250,000 was reflected in the current portion of deferred revenues. In addition, we recorded revenues related to the sale of a component of our IVUS catheter totaling \$606,000, \$904,000 and \$652,000 to Medtronic during the years ended December 31, 2007, 2006 and 2005, respectively. At December 31, 2007 and 2006, there was \$55,000 and \$5,000 due from Medtronic, respectively. The 2003 agreements with Medtronic also included an option to distribute agreement relating to certain other of our IVUS products not covered by the license described above. This option to distribute agreement provided Medtronic with the right to negotiate a new agreement for Medtronic to distribute certain of our IVUS products on terms to be mutually agreed upon by the parties upon the expiration, in June 2007, of our existing distribution agreement with Fukuda Denshi. The option to distribute agreement also provided that the terms of a new distribution agreement to be negotiated by us and Medtronic would be substantially similar to the terms of the existing distribution agreement with Fukuda. Under the option to distribute agreement, we were granted the right to terminate the agreement in the event that prior to December 31, 2006, we first consummated an initial public offering of shares of our common stock or sold all or substantially all of our assets, and then paid Medtronic a \$2,000,000 termination fee.

In January 2006, we and Medtronic entered into a termination agreement to terminate the option to distribute. We elected to terminate the option to distribute agreement because we believed we would gain greater flexibility in developing our product sales strategy in Japan if we did not have to consider the impact of Medtronic exercising the option to distribute or factor in the uncertainty of whether Medtronic would in fact exercise the option. In accordance with the termination agreement and in consideration of Medtronic agreeing to waive its right to the termination fee, we agreed to transfer to Medtronic an agreed amount of our inventory with a carrying value of approximately \$315,000. In the year ended December 31, 2006, \$315,000 was recorded in selling, general and administrative expense in the statement of operations in conjunction with the execution of this new agreement.

#### Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

#### Item 9A. Controls and Procedures

#### **Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of December 31, 2007, such disclosure controls and procedures were effective.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer as appropriate, to allow timely decisions regarding required disclosure.

#### Limitations on the Effectiveness of Controls

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

## Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth fiscal quarter ended December 31, 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# Management's Report on Internal Control Over Financial Reporting

As required by the SEC rules and regulations for the implementation of Section 404 of the Sarbanes-Oxley Act, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external reporting purposes in accordance with accounting principles generally accepted in the United States of America. Our internal control over financial reporting includes those policies and procedures that:

- (1) Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company,
- (2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and
- (3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements in our consolidated financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2007. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework*. Based on our assessments and those criteria, management determined that the Company maintained effective internal control over financial reporting as of December 31, 2007.

# Attestation Report of the Registered Public Accounting Firm

Ernst & Young LLP, our independent registered public accounting firm that has audited our financial statements included herein, has issued an attestation report on our internal control over financial reporting, which report is included under Item 8 of this Annual Report on Form 10-K.

# Item 9B. Other Information

None

#### PART III

#### Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2008 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our 2007 fiscal year (the "2008 Proxy Statement").

We have adopted the Volcano Corporation Code of Business Conduct and Ethics, a code of ethics that applies to all of our officers, directors, employees and consultants, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The Code of Business Conduct and Ethics is available on the Company's website at <a href="https://www.volcanocorp.com">www.volcanocorp.com</a>. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website, or as otherwise required by applicable law, rules or regulations.

# Item 11. Executive Compensation.

The information required by this Item is incorporated by reference to our 2008 Proxy Statement.

# Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item is incorporated by reference to our 2008 Proxy Statement.

## Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is incorporated by reference to our 2008 Proxy Statement.

# Item 14. Principal Accounting Fees and Services.

The information required by this Item is incorporated by reference to our 2008 Proxy Statement.

# PART IV

# Item 15. Exhibits, Financial Statement Schedules.

- (a) Index of Financial Statements:
  - (1) The financial statements required by Item 15(a) are filed in Item 8 of this Annual Report on Form 10-K.
  - (2) Schedules required by Item 15(a) are omitted because they are not required, are not applicable or the information is included in the consolidated financial statements or notes thereto.

#### (b) Index of Exhibits:

Exhibit

Number	Description
2.1	Asset Purchase Agreement dated July 10, 2003 by and among Jomed Inc., Jomed N.V., Jomed GmbH,
	Jomed Benelux S.A. and the Registrant (filed as Exhibit 2.1 to the Registrant's Registration Statement on
	Form S-1, as amended (File No. 333-132678), as originally filed on March 24, 2006, and incorporated
	herein by reference).

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- 4.1 Reference is made to Exhibits 3.1, 3.2 and 3.3.
- 4.2 Specimen Common Stock certificate of the Registrant (filed as Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A, as amended (File No. 333-132678), as originally filed on May 24, 2006, and incorporated herein by reference).
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- 10.1\* Form of Indemnification Agreement for directors, Chief Executive Officer and Chief Financial Officer (filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-132678), as originally filed on March 24, 2006, and incorporated herein by reference).
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- 10.3\* 2005 Equity Compensation Plan and forms of Stock Option Agreements and Stock Grant Agreement thereunder (2005 Equity Compensation Plan filed as Exhibit 10.3 to the Registrant's Registration Statement on Form S-1/A, as amended (File No. 333-132678), as originally filed on May 5, 2006, and incorporated herein by reference).
- 10.3a\* 2005 Equity Compensation Plan Form of Grantee Restriction Agreement (filed as Exhibit 10.3a to the Registrant's Annual Report on Form 10-K, as amended (File No. 000-52045), as originally filed on March 23, 2007, as amended, and incorporated herein by reference).
- 10.3b\* 2005 Equity Compensation Plan Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Agreement (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 000-52045), as originally filed on March 4, 2008, and incorporated herein by reference).
- License Agreement by and between the Registrant and The Cleveland Clinic Foundation, dated April 30, 2002 (filed as Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-132678), as originally filed on March 24, 2006, and incorporated herein by reference).
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- 10.9 Standard Industrial/ Commercial Multi-Tenant Lease, as amended, by and between 1325 "J" Street L.P. and Jomed Incorporated, dated January 16, 2001 (filed as Exhibit 10.20 to the Registrant's Registration Statement on Form S-1/A, as amended (File No. 333-132678), as originally filed on May 5, 2006, and incorporated herein by reference).
- 10.10† Supply Agreement by and between the Registrant and AVE Galway Limited, dated July 21, 2003 (filed as Exhibit 10.21 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-132678), as originally filed on March 24, 2006, and incorporated herein by reference).
- 10.11 License Agreement by and between the Registrant and AVE Galway Limited, dated July 21, 2003 (filed as Exhibit 10.22 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-132678), as originally filed on March 24, 2006, and incorporated herein by reference).
- 10.12† International Distributor Agreement by and between Cardiometrics, Inc., Goodman Company, Ltd. and Kaneko Enterprises, Inc., entered September 17, 1994 (filed as Exhibit 10.26 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-132678), as originally filed on March 24, 2006, and incorporated herein by reference).
- 10.13† Exclusive Distribution Agreement, as amended, by and between Goodman Company, Ltd. and the Registrant, dated September 27, 2004 (filed as Exhibit 10.27 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-132678), as originally filed on March 24, 2006, and incorporated herein by reference).
- 10.14† Supply and Distribution Agreement between General Electric Medical Systems Scs and the Registrant, dated March 16, 2006 (filed as Exhibit 10.28 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-132678), as originally filed on March 24, 2006, and incorporated herein by reference).

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10.16*	Managing Director Agreement by and between Volcano Europe NV and Michel Lussier, dated March 20, 2006 (filed as Exhibit 10.30 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-132678), as originally filed on March 24, 2006, and incorporated herein by reference).
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10.18†	Software Development and License Agreement by and between Paieon, Inc. and the Registrant dated May 10, 2006 (filed as Exhibit 10.32 to the Registrant's Registration Statement on Form S-1/A, as amended (File No. 333-132678), as originally filed on May 24, 2006, and incorporated herein by reference).
10.19*	Director Compensation Policy, as revised on August 27, 2007 (filed as Exhibit 10.19 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-52045), as originally filed on November 13, 2007, and incorporated herein by reference).
10.20*	2007 Commission Plan between the Registrant and Jorge Quinoy.
10.21*	Named Executive Officer Cash Compensation Arrangements.
12.1	Ratio of earnings to fixed charges
21.1	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (See signature pages hereto).
31.1	Certification of the President & Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
32.1**	Certification of the President & Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to

- † Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.
- \* Management contract or compensatory plan or arrangement.

Section 906 of the Sarbanes-Oxley Act of 2002.

\*\* The certifications attached as Exhibits 32.1 and 32.2 accompany this annual report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 14th day of March 2008.

Volcano Corporation

By: /s/ R. Scott Huennekens

R. Scott Huennekens President and Chief Executive Officer

#### POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints R. Scott Huennekens and John T. Dahldorf, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report on has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ R. Scott Huennekens R. Scott Huennekens	President and Chief Executive Officer and Director (principal executive officer)	March 14, 2008
/s/ John T. Dahldorf John T. Dahldorf	Chief Financial Officer (principal financial officer and principal accounting officer)	March 14, 2008
/s/ Olav B. Bergheim Olav B. Bergheim	Director	March 14, 2008
/s/ Connie R. Curran, RN, Ed.D. Connie R. Curran, RN, Ed.D.	Director	March 14, 2008
/s/ Kieran T. Gallahue  Kieran T. Gallahue	Director	March 14, 2008
/s/ Lesley H. Howe Lesley H. Howe	Director	March 14, 2008
/s/ Alexis V. Lukianov Alexis V. Lukianov	Director	March 14, 2008
/s/ Ronald A. Matricaria Ronald A. Matricaria	Director	March 14, 2008
/s/ John Onopchenko John Onopchenko	Director	March 14, 2008

#### **EXHIBIT INDEX**

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21.1	Subsidiaries of the Registrant.
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- † Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.
- \* Management contract or compensatory plan or arrangement.
- \*\* The certifications attached as Exhibits 32.1 and 32.2 accompany this annual report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

# Exhibit 21.1

# List of Volcano Corporation Subsidiaries

	Name	Jurisdiction
ì.	Volcano Japan Co., Ltd	Japan
2.	Volcano Europe, S.A./N.V.	Belgium
3.	Corazon Acquisition, Inc	Texas

# VOLCANO CORPORATION CERTIFICATIONS

- I, R. Scott Huennekens, certify that:
- 1. I have reviewed this annual report on Form 10-K of Volcano Corporation;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a
  material fact necessary to make the statements made, in light of the circumstances under which such statements
  were made, not misleading with respect to the period covered by this report;
- Based on my knowledge, the financial statements, and other financial information included in this report, fairly
  present in all material respects the financial condition, results of operations and cash flows of the registrant as of,
  and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2008 /s/ R. Scott Huennekens

R. Scott Huennekens
President & Chief Executive Officer
(principal executive officer)

# VOLCANO CORPORATION CERTIFICATIONS

- I, John T. Dahldorf, certify that:
- 1. I have reviewed this annual report on Form 10-K of Volcano Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2008 /s/ John T. Dahldorf

John T. Dahldorf Chief Financial Officer (principal financial officer)

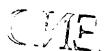
# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Volcano Corporation (the "Company") on Form 10-K for the period ended December 31, 2007, as filed with the Securities and Exchange Commission (the "Report"), I, R. Scott Huennekens, President & Chief Executive Officer of the Company, certify, pursuant to Rule 13a-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 14, 2008 /s/ R. Scott Huennekens

R. Scott Huennekens
President & Chief Executive Officer
(principal executive officer)



# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Volcano Corporation (the "Company") on Form 10-K for the period ended December 31, 2007, as filed with the Securities and Exchange Commission (the "Report"), I, John T. Dahldorf, Chief Financial Officer of the Company, certify, pursuant to Rule 13a-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 14, 2008 /s/ John T. Dahldorf

John T. Dahldorf Chief Financial Officer (principal financial officer)

